88-610 ①

IN THE

SUPREME COURT OF THE UNITED STATES

October Term, 1988

Supreme Court, U.S.
FILED
SEP 20 1988
JOSEPH F. SPANIOL, JR.
CLERK

No.______

S. ALLAN HURVITZ, MD, Petitioner

v.

OTIS R. BOWEN, Secretary, Department of Health and Human Services, Respondent.

PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE NINTH CIRCUIT

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200 pp

EDITOR'S NOTE

THE FOLLOWING PAGES WERE POOR HARD COPY AT THE TIME OF FILMING. IF AND WHEN A BETTER COPY CAN BE OBTAINED, A NEW FICHE WILL BE ISSUED.

I-A. QUESTIONS PRESENTED

1. REGARDLESS OF WHETHER OR NOT DR. HURVITZ RAISED OR PRESERVED HIS CONSTITUTIONAL CLAIMS IN ADMINISTRATIVE PROCEEDINGS, WHETHER REVIEWING COURT HAS DISCRETION TO CONSIDER CONSTITUTIONAL ISSUES, AND WHETHER IN THE CIRCUMSTANCES DISTRICT COURT AND THE COURT OF APPEALS FOR THE NINTH CIRCUIT SHOULD HAVE DONE SO?

2. WHETHER SANCTION IMPOSED BY RESPONDENT, SECRETARY OF DEPARTMENT OF HEALTH AND HUMAN SERVICES (hereinafter "Secretary"), AGAINST PETITIONER, DR. HURVITZ, WAS PROPER, REASONABLE, WARRANTED, LAWFUL AND NOT AN ABUSE OF DISCRETION?

3. WHETHER THERE WAS VIOLATION OF DR. HURVITZ'S RIGHT OF DUE PROCESS OF LAW UNDER FIFTH AND FOURTEENTH AMENDMENTS BY SECRETARY'S DECISION EXCLUDING ALL ITEMS AND SERVICES RENDERED BY HIM FROM REIMBURSEMENT UNDER MEDICARE PROGRAM FOR A PERIOD OF TWO

YEARS UNDER 42 USC 1395y, SECTION 1862(D)(1)(c), BASED ON MEDICARE TRANSMITTAL NO. 715(688) (hereinafter "Transmittal 715") [Exhibits R-1 & R-2, Excerpts - #6 & #7] AND ON ALLEGATION THAT VERTEBRAL ARTERY SURGERIES PERFORMED BY HIM ON 24 MEDICARE PATIENTS WERE UNNECESSARY, SINCE TRANSMITTAL 715 HAS NEVER BEEN PUBLISHED IN FEDERAL REGISTER , AND WAS ONLY ISSUED TO NULLIFY BLUE CROSS MEDICARE BULLETIN #146?

4. WHETHER IMPOSITION OF SANCTION ON DR. HURVITZ BY SECRETARY UNDER 42 USC 1395y, SECTION 1862(D)(1)(c) VIOLATED HIS DUE PROCESS RIGHTS, SINCE SAID REGULATION FAILS TO PROVIDE AN OBJECTIVE, FAIR PROCEDURE FOR DETERMINING WHETHER THE VERTEBRAL ARTERY SURGERIES WERE NECESSARY, AND WHETHER REGULATION SHOULD BE RULED INVALID AND UNCONSTITUTIONAL?

5. WHETHER DR. HURVITZ'S RIGHT TO FREEDOM OF SPEECH WAS VIOLATED BY SECRETARY'S DECISION EXCLUDING ALL ITEMS AND SERVICES RENDERED BY HIM FROM REIMBURSEMENT UNDER MEDICARE PROGRAM FOR A PERIOD OF TWO YEARS

BASED ON ALLEGATION THAT VERTEBRAL ARTERY SURGERIES PERFORMED BY HIM ON 24 MEDICARE PATIENTS WERE UNNECESSARY, AND WHETHER HIS PUBLISHED AND NON-PUBLISHED IDEAS OF MEDICAL RESEARCH REGARDING DIAGNOSIS OF VERTEBRAL-BASILAR ARTERY INSUFFICIENCY OF BRAINSTEM (HEREINAFTER "VBAI") AND SURGICAL TREATMENT OF SYMPTOMATIC VBAI WITH VERTEBRAL ARTERY SURGERY ARE PROTECTED BY THE FREEDOM OF SPEECH CLAUSE IN FIRST AMENDMENT?

6. WHETHER THERE WAS AN ABUSE OF DISCRETION IN THAT PROFESSIONAL STANDARDS REVIEW ORGANIZATION (hereinafter "PSRO") AREA 22 HAD NO AUTHORITY TO REVIEW PART B SERVICES OF PHYSICIANS, INCLUDING VERTEBRAL ARTERY SURGERY DONE BY DR. HURVITZ, AND HAD NO AUTHORITY TO WITHDRAW WAIVER OF LIABILITY FOR VERTEBRAL ARTERY SURGERY FROM DR. HURVITZ, WHICH WOULD INVALIDATE SANCTION IMPOSED BY SECRETARY?

7. WHETHER THE ADVERSE FINDINGS AND ADVERSE CONCLUSIONS IN SECRETARY'S FINAL DECISION ARE NOT SUPPORTED BY SUBSTANTIAL EVIDENCE AND WHETHER HER DECISION IS

UNLAWFUL?

8. WHETHER SECRETARY'S FINAL DECISION IS UNLAWFUL AND WHETHER HER SANCTION OF DR. HURVITZ, HER ADVERSE FINDINGS AND ADVERSE CONCLUSIONS ARE ARBITRARY, CAPRICIOUS, AN ABUSE OF DISCRETION, OTHERWISE NOT IN ACCORDANCE WITH LAW - CONTRARY TO CONSTITUTIONAL RIGHT, POWER AND PRIVILEGE - IN EXCESS OF STATUTORY JURISDICTION, AUTHORITY, LIMITATION, AND SHORT OF STATUTORY RIGHT - WITHOUT OBSERVANCE OF PROCEDURE REQUIRED BY LAW - AND UNWARRANTED BY THE FACTS?

9. WHETHER FINDING AND CONCLUSION OF ALJ IN HIS DECISION AND IN FINAL DECISION OF SECRETARY THAT DR. HURVITZ MET AND COMPLIED WITH REQUIREMENT OF CONDITION 3 OF TRANSMITTAL 715 COMPLETELY EXONERATES HIM [Certified Administrative Record (hereinafter "CAR") page 553; Appendix hereto, pp.A104-106], SINCE SECRETARY'S INITIAL DECISION TO EXCLUDE DR. HURVITZ FROM REIMBURSEMENT UNDER MEDICARE PROGRAM WAS ISSUED FOR ONE SPECIFIC STATED REASON --

SECRETARY'S INITIAL ALLEGATION [Exh.R-7, CAR 6482; Appendix hereto, p.A128] THAT DR. HURVITZ FAILED TO MEET CONDITION 3 OF TRANSMITTAL 715? CONDITION 3 REQUIRES PRESENCE OF RADIOGRAPHIC EVIDENCE OF VALID VERTEBRAL ARTERY OBSTRUCTION IN MEDICARE PATIENTS ON WHOM VERTEBRAL ARTERY SURGERY IS PERFORMED TO QUALIFY FOR MEDICARE PAYMENT [Exhs.R-1 & R-2, CAR 6451, 6455; Excerpts-#6 & #7].

10. WHETHER ALJ'S DECISION AND FINAL DECISION OF SECRETARY WERE IN ERROR, SINCE THEY FOUND THAT DR. HURVITZ FAILED TO COMPLY WITH CONDITION 1 OF TRANSMITTAL 715 (symptoms of vertebral artery obstruction exist) AND WITH CONDITION 2 OF TRANSMITTAL 715 (other causes have been considered and ruled out), AND WHETHER THE RECORD COMPELLS THE FINDING THAT DR. HURVITZ COMPLIED WITH CONDITIONS 1 AND 2 , SINCE HE SUBMITTED TO APPEALS COUNCIL A COMPREHENSIVE DISCUSSION OF THE HOSPITAL CHART OF EACH OF THE 24 SUBJECT PATIENTS CLEARING SHOWING THAT HE MET CONDITIONS 1 AND 2 [CAR 306-495, Docket #8; copies of these

Comprehensive Discussions, along with pertinent parts of the hospital charts from the Certified Administrative Record of each patient, CAR 8469-9847, were submitted to the Appellate Court in Petitioner's Request for Rehearing as Appendices B & A]?

11. WHETHER DR. HURVITZ WAS DENIED ADEQUATE NOTICE UNDER DUE PROCESS CLAUSES OF FIFTH AND FOURTEENTH AMENDMENTS OF ALL CHARGES AGAINST HIM, INCLUDING THOSE CHARGES (ADVERSE FINDINGS) STATED IN FINAL DECISION OF SECRETARY; WHETHER HE WAS NOT APPRISED IN ADVANCE OF THE PARTICULAR CHARGES THAT HE HAD NOT COMPLIED WITH CONDITIONS 1 AND 2 OF TRANSMITTAL 715 AND WAS NOT PERMITTED ADEQUATE PREPARATION FOR THE HEARING BEFORE ALJ; AND WHETHER THIS CONSTITUTED IRREPARABLE HARM AND LOSS OF HIS CONSTITUTIONAL RIGHT OF ADEQUATE NOTICE UNDER SAID DUE PROCESSES CLAUSES?

12. WHETHER DR. HURVITZ WAS SUBJECTED TO A HEARING BEFORE ALJ WITHOUT RECEIVING NOTICE IN ADVANCE OF ALL CHARGES LODGED AGAINST HIM, INCLUDING THOSE CHARGES (ADVERSE FINDINGS)

STATED IN FINAL DECISION OF SECRETARY; WHETHER HE WAS NOT APPRISED IN ADVANCE OF THE PARTICULAR CHARGES THAT HE HAD NOT COMPLIED WITH CONDITIONS 1 AND 2 OF TRANSMITTAL 715, TO WHICH HE HAD TO DEFEND AGAINST, AND WHETHER THEREFORE HE WAS DENIED HIS RIGHT TO A FAIR HEARING BEFORE ALJ; AND WHETHER THIS CONSTITUTED IRREPARABLE HARM AND LOSS OF HIS CONSTITUTIONAL RIGHTS OF DUE PROCESS AND FAIR TREATMENT BY THE GOVERNMENT?

13. WHETHER PSRO AREA 22, HEALTH CARE FINANCE ADMINISTRATION (hereinafter "HCFA") AND SECRETARY VIOLATED DR. HURVITZ'S PROCEDURAL DUE PROCESS PROTECTIONS, WHICH APPLY WHERE THERE HAS BEEN INTERFERENCE WITH A PROPERTY RIGHT? WHETHER THEIR ACTIONS VIOLATED HIS CONSTITUTIONAL RIGHTS AND WHETHER THEY ACTED WITH MALICIOUS INTENTION TO CAUSE HIM DEPRIVATION OF HIS CONSTITUTIONAL RIGHTS AND OTHER INJURY?

14. WHETHER SECRETARY AND HCFA FAILED TO PROVE THAT THE TWO YEAR SANCTION AGAINST DR. HURVITZ WAS LEGALLY ARRIVED AT OR LEGALLY IMPOSED, AND WHETHER THERE IS CLEAR EVIDENCE

OF NON-COMPLIANCE WITH MANDATORY PROCEDURES AND STANDARDS FOR IMPOSING SUCH A SANCTION WITH DENIAL OF PROCEDURAL DUE PROCESS OF LAW? WHETHER IT WAS AN ERROR FOR SECRETARY AND ALJ TO HAVE SUMMARILY DISPOSED OF THESE IMPORTANT PROCEDURAL ISSUES, AND WHETHER IT WAS AN ERROR FOR SECRETARY TO FIND THAT MANDATORY PROCEDURES FOR IMPOSING THE SANCTION HAD NOT BEEN VIOLATED IN DR. HURVITZ'S CASE?

15. WHETHER DR. HURVITZ'S CONSTITUTIONAL RIGHT TO A SPEEDY, FAIR TRAIL (HEARING) WAS VIOLATED BY ALJ?

16. WHETHER SECRETARY AND HCFA FAILED TO SUPPORT WITH SUBSTANTIAL EVIDENCE THAT DR. HURVITZ HAD NOT COMPLIED WITH CONDITIONS 1 AND 2 OF TRANSMITTAL 715, WHERE HCFA RELIED FOR PRESENTATION OF ITS CASE ALMOST EXCLUSIVELY UPON TESTIMONY FROM UNQUALIFIED WITNESSES WHO HAD NO INTEREST IN AND WHO HAD NO KNOWLEDGE OF THE DIAGNOSIS AND SURGICAL TREATMENT OF VERTEBRAL ARTERY INSUFFICIENCY/OBSTRUCTION AND WHO DID NOT TREAT OR EXAMINE ANY OF THE 24 SUBJECT PATIENTS? WHETHER IT WAS AN ERROR FOR ALJ

AND SECRETARY TO HAVE ACCEPTED THE TESTIMONY OF HCFA'S UNQUALIFIED, NON-EXPERT WITNESSES WITH RESPECT TO DR. HURVITZ'S COMPLIANCE WITH CONDITIONS 1 AND 2?

17. WHETHER THE PART OF FINAL DECISION OF SECRETARY WHICH STATES THAT VERTEBRAL ARTERY SURGERY PERFORMED BY DR. HURVITZ ON CERTAIN MEDICARE PATIENTS WAS NOT REASONABLE OR NECESSARY BECAUSE HE FAILED TO COMPLY WITH CONDITIONS 1 AND 2 OF TRANSMITTAL 715, REPRESENTS AN ABUSE OF DISCRETION, SINCE UNDER MEDICARE PROVISIONS, CONGRESS INTENDED THAT RESPONSIBILITY FOR DETERMINING WHAT SERVICES A PATIENT REQUIRES IS TO REST PRIMARILY WITH THE TREATING PHYSICIAN, AND THAT THE TREATING PHYSICIAN'S DECISION IS TO BE GIVEN GREAT WEIGHT AS STATED BY THE COURT IN BREEDEN V. WEINBERGER, 377 F.Supp. 734 (D.C.La. 1974)?

18. WHETHER THE PARTS OF DECISIONS OF ALJ [CAR 532-556, Appendix hereto] AND APPEALS COUNCIL [CAR 15-23, Appendix hereto], AND THE PART OF FINAL DECISION OF SECRETARY THAT FIND THAT DR. HURVITZ FAILED TO COMPLY

WITH CONDITIONS 1 AND 2 OF TRANSMITTAL 715 ARE NOT SUPPORTED BY SUBSTANTIAL EVIDENCE, AND ARE CLEARLY ERRONEOUS AND CONTRARY TO OVERWHELMING EVIDENCE?

19. WHETHER THE ADVERSE FINDINGS OF FINAL DECISION OF SECRETARY ARE NOT SUPPORTED BY SUBSTANTIAL EVIDENCE, AND WHETHER THE RESULTS OF HER FINAL DECISION ARE NOT CONSISTENT WITH CONGRESSIONAL INTENT AND ARE NOT CONSISTENT WITH ELEMENTAL FAIRNESS?

20. WHETHER DECISIONS OF ALJ AND APPEALS COUNCIL AND FINAL DECISION OF SECRETARY FAILED TO TAKE ALL EVIDENCE INTO ACCOUNT AND REJECTED EVIDENCE THAT CONFLICTS WITH THEIR ADVERSE FINDINGS OF FACT, REGARDING THEIR FINDINGS THAT DR. HURVITZ FAILED TO COMPLY WITH CONDITIONS 1 AND 2 OF TRANSMITTAL 715 AND THAT HIS TWO YEAR SANCTION WAS REASONABLE?

21. WHETHER ALJ, APPEALS COUNCIL AND SECRETARY DISREGARDED AND REJECTED IRREFUTABLE, OVERWHELMING EVIDENCE CLEARLY RECORDED IN THE OPERATIVE REPORTS THAT SIGNIFICANT PARTIAL OBSTRUCTION OF THE

OPERATED VERTEBRAL ARTERY EXISTED AND WAS FOUND AT SURGICAL OPERATION IN ALL 24 PATIENTS?

22. WHETHER ALJ, APPEALS COUNCIL AND SECRETARY DISREGARDED AND REJECTED OVERWHELMING EVIDENCE THAT THE TISSUE THAT WAS OBSTRUCTING THE VERTEBRAL ARTERY IN THE 24 PATIENTS WAS REMOVED BY DR. HURVITZ AND SENT TO THE HOSPITAL PATHOLOGIST, WHO ISSUED A FORMAL REPORT CONTAINING GROSS AND MICROSCOPIC DESCRIPTIONS OF THE OBSTRUCTING TISSUE WITH THE DIAGNOSIS?

23. WHETHER ALJ, APPEALS COUNCIL AND SECRETARY DISREGARDED AND REJECTED OVERWHELMING EVIDENCE THAT ASSISTANT SURGEON, ROBERT I. KATZ, MD, WITNESSED AND CONFIRMED EXISTENCE OF SIGNIFICANT PARTIAL OBSTRUCTION OF VERTEBRAL ARTERY IN THE 24 PATIENTS, AND WITNESSED AND CONFIRMED THE FACT THAT DR. HURVITZ CORRECTED THE VERTEBRAL ARTERY OBSTRUCTION IN THE 24 SUBJECT PATIENTS BY THE SURGERIES AS DESCRIBED IN THE OPERATIVE REPORTS?

24. WHETHER ALJ, APPEALS COUNCIL AND

SECRETARY DISREGARDED AND REJECTED OVERWHELMING EVIDENCE THAT EACH PATIENT HAD POST-OPERATIVE IMPROVEMENT RECORDED IN HIS HOSPITAL CHART AND DESCRIBED IN THE TYPED AND SIGNED 'DISCHARGE SUMMARY', WHICH FURTHER CONFIRMED THE DIAGNOSIS OF VERTEBRAL-BASILAR ARTERY INSUFFICIENCY AND VERTEBRAL ARTERY OBSTRUCTION [See Appendix A of Petition for Rehearing before the Appellate Court, which includes Discharge Summary, History and Physical Examination, Physical Therapist's Report of patient's pre-operative and post-operative grip testing, and Operative Report from each patient's hospital chart, CAR 8469-9847]?

25. WHETHER APPEALS COUNCIL AND SECRETARY DISREGARDED AND REJECTED THE SECOND FAVORABLE DECISION OF ALJ DATED APRIL 23, 1984 AND OVERWHELMING EVIDENCE IN THAT DECISION REGARDING PATIENT GAIL MORRIS [CAR 10975-10986, Docket #18]?

26. WHETHER HCFA FAILED, IN EACH OF THE 24 PATIENT-CASES, TO SUPPORT BY SUBSTANTIAL EVIDENCE THAT EITHER, (1) SYMPTOMS OF

VERTEBRAL ARTERY OBSTRUCTION DID NOT EXIST, OR (2) THAT OTHER CAUSES HAD NOT BEEN CONSIDERED AND RULED OUT PRIOR TO VERTEBRAL ARTERY SURGERY, WHETHER HCFA SPECIFICALLY FAILED IN EACH CASE TO SUPPORT WITH SUBSTANTIAL EVIDENCE THAT THE PATIENTS HAD THE ALTERNATIVE DISEASE SUGGESTED BY HCFA, MULTIPLE SCLEROSIS, AND WHETHER IT WAS THEREFORE AN ERROR FOR SECRETARY TO FIND THAT DR. HURVITZ HAD NOT COMPLIED WITH CONDITIONS 1 AND 2 OF TRANSMITTAL 715?

27. WHETHER THE GOVERNMENT AND HCFA CHOSE TO BASE ITS CASE ON EXTRANEOUS GROUNDS AND ON A FALSE ISSUE, WHICH ALJ AND SECRETARY ERRONEOUSLY ACCEPTED, NAMELY, THAT THE 24 PATIENTS HAD MULTIPLE SCLEROSIS AND THAT MULTIPLE SCLEROSIS HAD NOT BEEN RULED OUT?

28. WHETHER SECRETARY AND ALJ HAD DOUBT OF EXISTENCE OF MULTIPLE SCLEROSIS IN THE 24 PATIENTS?

29. WHETHER THERE WAS ABUSE OF DISCRETION IN THAT ALJ AND SECRETARY EXCEEDED THEIR EXPERTISE IN MEDICAL MATTERS BY REJECTING THE "SYMPTOMS OF VERTEBRAL ARTERY

OBSTRUCTION" (CONDITION 1) DESIGNATED IN TRANSMITTAL 715 AND BY ESTABLISHING THEIR OWN "SYMPTOMS OF VERTEBRAL ARTERY OBSTRUCTION"?

30. WHETHER THERE WAS ABUSE OF DISCRETION IN THAT ALJ AND SECRETARY EXCEEDED THEIR EXPERTISE IN MEDICAL MATTERS BY REJECTING THE "OTHER CAUSES TO BE CONSIDERED AND RULED OUT" (CONDITION 2) DESIGNATED IN TRANSMITTAL 715 AND BY ESTABLISHING THEIR OWN "OTHER CAUSES TO BE CONSIDERED AND RULED OUT"?

31. WHETHER THERE WAS ABUSE OF DISCRETION IN THAT ALJ AND SECRETARY EXCEEDED THEIR EXPERTISE IN MEDICAL MATTERS BY REJECTING THE FACT THAT SYMPTOMS OF VERTEBRAL ARTERY OBSTRUCTION CAN BE CHRONIC IN NATURE AS ARTICULATED BY TRANSMITTAL 715, AND BY DECLARING THAT SYMPTOMS OF VERTEBRAL ARTERY OBSTRUCTION CAN ONLY BE TRANSIENT IN NATURE?

32. WHETHER THERE WAS ABUSE OF DISCRETION IN THAT DR. EARLE J. MAILE, VICE-PRESIDENT AND MEDICAL DIRECTOR OF BLUE CROSS OF SOUTHERN CALIFORNIA (BLUE CROSS BEING THE PART A MEDICARE INTERMEDIARY HAVING

AUTHORITY OVER MEDICARE PAYMENT TO HOSPITALS AND NOT TO PHYSICIANS), HAD NO AUTHORITY TO UNILATERALLY ISSUE MEDICARE BULLETIN 146 [Exh. A-153, CAR 10333-10334, Excerpts - #3] ON SEPTEMBER 22, 1976 REGARDING VERTEBRAL ARTERY SURGERY (A MEDICARE PART B SERVICE) STATING THAT VERTEBRAL ARTERY SURGERY WAS INVESTIGATIONAL AND NOT COVERED BY THE MEDICARE PROGRAM?

33. WHETHER DR. HURVITZ'S HEARING BEFORE ALJ WAS CONDUCTED AS AN ADVERSARY PROCEDURE, WHICH WOULD VIOLATE THE LAW?

34. WHETHER THE ADVERSE PARTS IN FINAL DECISION OF SECRETARY WERE NOT WARRANTED BY THE RECORD, VIEWING THAT RECORD AS A WHOLE, WHETHER THEY DO NOT HAVE A REASONABLE BASIS IN LAW, AND WHETHER PROPER LEGAL SIGNIFICANCE HAS NOT BEEN AFFORDED TO PRIMARY EVIDENTIARY FACTS?

35. WHETHER CAREFUL SCRUTINY OF ENTIRE RECORD SHOWS THAT THERE IS NOT A SOUND FOUNDATION FOR SECRETARY'S FINAL ADVERSE FINDINGS AND THAT THOSE ADVERSE FINDINGS ARE NOT RATIONAL?

36. WHETHER ADVERSE PARTS OF FINAL DECISION OF SECRETARY ARE BASED ON CONCLUSIONS NOT REASONABLY REACHED ON DUE CONSIDERATIONS OF ALL RELEVANT ISSUES PRESENTED, APPLIES ARBITRARY STANDARDS, MISINTERPRETS PROVISIONS OF APPLICABLE FEDERAL STATUTES AND REGULATIONS, AND MISCONSTRUES OTHER APPLICABLE LAW?

37. WHETHER ABSENCE FROM THE RECORD REVIEWED BY APPEALS COUNCIL OF THE MATERIAL AND CENTRAL DOCUMENT REGARDING TRANSMITTAL 715, EXHIBIT C-10 [Excerpts #16], "ORDER AMENDING RESULTS OF PREHEARING CONFERENCE", PRESENTS A PROCEDURAL DEFECT AND IS PREJUDICIAL?

I-B. LIST OF PARTIES WHOSE JUDGMENT IS SOUGHT TO BE REVIEWED :

Ninth Circuit Court of Appeals, United States District Court for Central District of California, Secretary of Health and Human Services, Appeals Council, Administrative Law Judge.

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IN THE

SUPREME COURT OF THE UNITED STATES

October Term, 1988

No.______

S. ALLAN HURVITZ, MD, Petitioner

v.

OTIS R. BOWEN, Secretary, Department of Health and Human Services, Respondent.

PETITION FOR WRIT OF CERTIORARI TO UNITED STATES COURT OF APPEALS FOR THE NINTH CIRCUIT

Petitioner, S. Allan Hurvitz, MD, respectfully prays that a writ of certiorari issue to review judgment and opinion of Ninth Circuit Court of Appeals, entered and filed in this proceeding on May 23, 1988; Appellate Court No. 87-5682. This was an appeal of Summary Judgment of United States District Court for Central District of California entered on February 25, 1988, D.C. No. CV 85-1590 JSL. Denial of Petition for

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Rehearing before Court of Appeals was entered on June 23, 1988.

II. OPINIONS BELOW

Opinion and judgment of Court of Appeals will not be published and appears in Appendix hereto beginning on page A2. Summary Judgment of District Court appears in Appendix hereto beginning on pages A7 and A10. Decision of Appeals Council, which adopted decision of Administrative Law Judge (hereinafter "ALJ") and whose decision became the final decision of Secretary, Department of Health and Human Services (hereinafter "Secretary"), appears in Appendix hereto beginning on page A34. Decision of ALJ appears in Appendix hereto beginning on page A57. Secretary's initial decision-sanction, Exhibit R-7 [CAR 6474, 6475, 6482], appears in Appendix hereto beginning on page A124.

III. JURISDICTION

Summary Judgment of District Court was entered February 25, 1987; Notice of Appeal was filed March 2, 1987. Opinion and judgment of Court of Appeals was entered on

May 23, 1988. A timely Petition for Rehearing before Court of Appeals was denied on June 23, 1988, and this petition for writ of certiorari was originally filed in a timely fashion on September 20, 1988 with the fee of $200 (within 90 days of June 23, 1988), but was returned by the Clerk of this Court for correction of format and was again filed within 21 days of receipt of returned 39 copies of original petition for writ of certiorari.

This action arises under provisions of Social Security Act. Jurisdiction to review is conferred by 42 USC Section 405(g), and is also conferred and governed by Administrative Procedures Act, Sections 551 *et seq.* and 701 *et seq.* of Title 5, specifically USC Sections 701 through 706. Jurisdiction is also conferred by 42 USC 1395y(d)(3), 42 USC 1291, and 28 USC 1257.

In *Julian v. Folsom,* D.C.N.Y. 1958, 160 F.Supp. 747, court ruled that Administrative Procedure Act, Sections 551 *et seq.* and 701 *et seq.* of Title 5, respecting judicial

review of agency actions, must be read in pari materia with 42 USC Section 405, and review to be made of a final decision of Secretary must meet standards set by said Act, Sections 501 et seq. and 701 et seq. of Title 5. In Miller v. Ribicoff, D.C.S.C. 1961, 195 F.Supp. 534 and Couch v. Udall, D.C.Okla. 1967, 265 F.Supp. 848, courts ruled that 42 USC Section 405 and Administrative Procedure Act, Sections 551 et seq. and 701 et seq. of Title 5, must be read in pari materia for judicial review of actions of administrative agencies.

IV. LAW INVOLVED

Federal Law involved includes United States Constitution, the First, Fifth and Fourteenth Amendments to the Constitution, 42 USC 1395y Section 1862(D)(1)(c), as well as Administrative Procedures Act, Sections 551 et seq. and 701 et seq. of Title 5, specifically USC Sections 701 through 706. Involved is Social Security Act 216(i),

223(c,d), (d)(5) as amended 29 USCA 416(i) 423(c,d)(d)(5), regarding issue of adversary procedure.

V. PARTIES

Dr. Hurvitz graduated from Boston University School of Medicine in 1955, and has been licensed to practice medicine in California since 1956. He completed a four-year Residency in General Surgery in 1960 [Exh. A-49, CAR 8456], and a two-year Residency in Thoracic & Cardiovascular Surgery in 1964 [Exh. A-50, CAR 8457-8458]. He is an expert in diagnosis and surgical treatment of symptomatic vertebral artery obstruction and of vertebral-basilar artery insufficiency of the brainstem. Dr. Hurvitz is Board-certified as a Diplomate of both the American Board of Surgery [Exh. A-51, CAR 8459] and the American Board of Thoracic Surgery [Exh. A-52, CAR 8460]. He is a founding member of Society for Neurovascular Surgery, a Fellow of American College of Angiology, and a member of Society of Thoracic Surgeons [Exh. A-55, CAR 8463] and

Western Thoracic Surgical Association [Exh. A-56, CAR 8464]. Prior to his hearing before ALJ, Dr. Hurvitz had performed numerous vertebral artery surgeries during his career and had published articles on vertebral artery surgery in journals, Surgery, Gynecology and Obstetrics, Vascular Surgery and American Surgeon [Exh. A-91, CAR 9869-9875; Exh. A-92, CAR 9808-9914; Exh. A-93, CAR 9991-9994]. In a favorable Medicare decision regarding vertebral artery surgery done by Dr. Hurvitz, ALJ Mallory C. Walker stated that Dr. Hurvitz is "a highly qualified thoracic and cardiovascular surgeon" [Exh. A-142, CAR 10182].

Respondent Otis R. Bowen is the Secretary, DHHS and is charged with administration of Title XVIII of Social Security Act, 42 USC 1395, et seq., the Medicare Program.

VI. STATEMENT OF FACTS AND PROCEEDINGS

1. Dr. Hurvitz filed this action in District Court on March 8, 1985, to obtain judicial review of final decision of

Secretary excluding him for a period of two years beginning on August 13, 1980 from receiving federal funds under Medicare Program for all medical services he provided to all Medicare patients, which eliminated a substantial portion of his income. Secretary issued an initial decision-sanction [Exh. R-7, Appendix hereto] on July 29, 1980 under 42 USC 1395y, Section 1862(D)(1(c) to exclude all items and services rendered by Dr. Hurvitz from reimbursement under Medicare Program for two years, which began on August 13, 1980 and which is still in effect.

2. On July 16, 1982, Dr. Hurvitz requested reinstatement of his eligility to participate in Medicare Reimbursement Program, which was denied by Secretary on November 2, 1983, through Office of Inspector General, Department of Health and Human Services (hereinafter "DHHS") [Docket #1, Complaint, page 15, lines 22-25].

3. On recommendation of Professional Standards Review Organization (hereinafter "PSRO") Area 22, Secretary issued a two-year

exclusion sanction of Dr. Hurvitz in her initial decision letter of July 29, 1980 [Appendix hereto, Exh. R-7, CAR 6482] because of his alleged failure, in certain patients on whom he performed vertebral surgery, to comply with the requirement of Condition 3 (xray evidence of valid vertebral artery obstruction) of Transmittal 715.

4. Since Dr. Hurvitz believed that Secretary's sanction against him was unconstitutional and illegal, he requested a hearing before an ALJ.

5. On January 28, 1981, during the Prehearing Conference, HCFA's Attorney notified ALJ: "Well, you can't create a whole new ballgame. You have to go on the facts that were considered by the PSRO and the Secretary" [CAR 53-54, Docket #8].

6. On March 10, 1981, ALJ issued an "Order Setting Forth Results of Prehearing Conference": "That the issue to be resolved is whether or not it was a reasonable exercise of the discretion of the Secretary of Health and Human Services..., for the

Secretary to determine on July 29, 1980, that all items and services provided by Appellant should be excluded effective August 13, 1980, for a period of two (2) years from coverage in the Federal Medicare Program ..." [Exh. C-3, CAR 10770-10771, Excerpts - #15].

7. ALJ ruled in his decision that Dr. Hurvitz did indeed comply with the requirement of Condition 3 of Transmittal 715 [CAR 553, Appendix hereto], that Dr. Hurvitz did comply with Condition 4 (no contraindications to vertebral surgery) [CAR 555], but failed to comply with Conditions 1 and 2 of Transmittal 715. In other words, ALJ upheld sanction on his own determination, and on other grounds than that stated by Secretary in her initial decision-sanction letter of July 29, 1980.

8. Dr. Hurvitz requested review of ALJ's decision by Appeals Council. Appeals Council adopted findings and conclusions of ALJ and held that determinations by Secretary to exclude Dr. Hurvitz from all Medicare reimbursement for two years was reasonable

and proper and in accordance with applicable Law and Regulations, and issued its decision on January 14, 1985 [CAR 15-23, Appendix hereto]. Decision of Appeals Council became final decisiòn of Secretary.

9. In her initial decision-sanction letter of July 29, 1980, Secretary, through HCFA, stated there was only one reason for sanction against Dr. Hurvitz -- that he failed only to meet Condition 3 of Medicare Transmittal 715 [Exh. R-7, CAR 6482, Appendix hereto]. Finding and conclusion of ALJ in his decision [CAR 553, Appendix hereto] and in final decision of Secretary that Dr. Hurvitz met and complied with requirement of Condition 3 of Transmittal 715 in the 24 patient-cases, completely exonerates him.

10. Sanction of Dr. Hurvitz can be traced to a decision reached by Earle J. Maile, MD, Medical Director, Blue Cross of Southern California (fiscal intermediary for Part A of Medicare Program), in September, 1976, concerning vertebral artery surgery to relieve VBAI: "On the basis of comments and

recommendations from our surgical consultants, including specialists in the field of vascular surgery, we have determined that these procedures are investigational and not in accord with recognized standards of medical practice." [Exh. A-153(1), CAR 10328, Excerpts - #1]

11. On September 22, 1976, Blue Cross of Southern California unilaterally issued Medicare Bulletin No. 146: "All providers are hereby notified that vertebral artery surgery has been determined to be an investigational procedure not in accord with recognized standards of medical practice. As such, it is excluded from Medicare program coverage" [Exh. A-153(4), CAR 10333-10334, Excerpts - #3]..

12. Dr. Hurvitz asked Dr. Maile to provide him with names of his surgical consultants and copies of their statements regarding vertebral artery surgery, but Dr. Maile refused. Subsequently Dr. Hurvitz received a response in a letter dated January 23, 1977 from James B. Cardwell, Commissioner

of Social Security: "It is my understanding that Blue Cross of Southern California has received no general statements about vertebral artery surgery from its consultants." [Exh. 153(6), CAR 10337-10338, Docket #18]

13. Dr. Hurvitz submitted issue of vertebral artery surgery to California Medical Association (hereinafter "CMA") in October, 1976. CMA's Advisory Panel on General Surgery & Neurosurgery concluded that vertebral artery surgery was "accepted medical practice" [Exh. A-108; CAR 3560-3564, 10059; Excerpts - #5].

14. Dr. Hurvitz requested Roger O. Egeberg, MD, Chief Medical Officer of Medicare, to instruct Dr. Maile of Blue Cross to withdraw Bulletin No. 146. Wiley F. Barker, MD, Professor of Surgery, UCLA School of Medicine, Los Angeles, spearheaded the effort to overturn Blue Cross Bulletin 146; in his letter to Medicare dated November 19, 1976 [Exh. R-104, CAR 7885, Excerpts - #4], Dr. Barker states: "I have received some

documentation of some information which horrifies me. This concerns Bulletin 146..., which states that vertebral artery surgery has been determined to be an investigational procedure not in accord with recognized standards of medical practice. This is balderdash! It has been a standard operation in the hands of competent vascular surgeons for almost 20 years." Numerous other vascular surgeons wrote letters to Medicare and to Dr. Maile, echoing the sentiments of Dr. Barker [CAR 7873, 7875, 7877, 7878, 7880-7882, 7888, Docket #15]. It was U.S. Senator Alan Cranston of California, who finally succeeded in forcing Medicare to take positive action regarding vertebral artery surgery coverage in Southern California [CAR 7826-7829, Docket #15].

15. Two years after issuance of Bulletin 146, Medicare, on September 1, 1978 issued identical Transmittal Numbers 715 [for Medicare Part A, Exh. R-1, CAR 6450-6453; Excerpts - #6] and 688 [for Part B, Exh. R-2, CAR 6454-6457, Excerpts - #7]. Since

Medicare Transmittals 715 and 688 are identical, we will hereafter refer only to Transmittal No. 715. Transmittal 715 states that vertebral *is covered* by the Medicre Program, it designates the *symptoms* which are to considered evidence of vertebral artery obstruction (condition 1), and it designates the other causes to be considered and ruled out prior to surgery (condition 2). Transmittal 715 states that vertebral surgery can be medically reasonable and necessary (and therefore payable) if each following condition is met: (1) symptoms of vertebral artery obstruction exist; (2) other causes have been considered and ruled out; (3) *there is radiographic evidence of a valid vertebral artery obstruction* ; and (4) contraindications to the procedure do not exist.

16. On December 27, 1978 a letter was sent from PSRO Area 22 to Century City Hospital: "In accordance with Medicare Bulletin #146, vertebral artery surgery is an exclusion and has been determined to be an

investigational procedure not in accordance with recognized standards of medical practice." [Exh. A-106, CAR 3555-3560, 10052-10053; Excerpts - Document #8]. District Court ERRED in its statement on page 7, lines 3 through 6, of Statement of Uncontroverted Facts and Conclusions of Law [Appendix hereto]: "Plaintiff has never alleged that Medicare Bulletin 146 was relied upon by the PSRO and the Secretary to exclude, and thus its relevance (as well as plaintiff's intent in raising the issue) is questionable." In his Memorandum on page 28, lines 9-15, Docket #49, Dr. Hurvitz does indeed state that PSRO relied upon Bulletin 146.

17. Administrator at Century City Hospital submitted the December 27, 1978 letter from PSRO Area 22 to Dr. Hurvitz, asking that he act on it. On January 26, 1979 Dr. Hurvitz sent a letter to Mildred L. Tyssowski, Acting Director of Medicare Bureau, requesting that PSRO Area 22 be instructed to carry out Medicare Transmittal

No. 688(715) on vertebral artery surgery. On behalf of Ms. Tyssowski, on April 13, 1979 Mr. Wayne Moon of Medicare responded to Dr. Hurvitz's letter: "Medicare Transmittal 688 is a revision to the Medicare Carriers Manual. As such, it relates to those services (physician as well as other outpatient services) that are covered under the Medicare supplementary insurance plan (Part B). To date, neither Area 22 PSRO nor any other California PSRO has received approval to review physician inpatient services under Part B of the Medicare Program" [Exh. A-45, CAR 8450-8451, Excerpts - #9].

18. On February 15, 1979, PSRO Area 22 unlaterally advised Century City Hospital that waiver of liability for Dr. Hurvitz would be withdrawn effective Feb. 20 ,1979 [Exh. R-35 , CAR 6874, Docket #14]. PSRO Area 22 had determined that there was an alleged violation of obligation by Dr. Hurvitz, but failed to give written notice to him of said alleged violation, and

immediately imposed a sanction on him (withdrawal of waiver of liability).

19. On May 16, 1979, Reconsideration Committee of PSRO Area 22 met to reconsider Century City Hospital stays of four patients on whom Dr. Hurvitz performed vertebral artery surgery between February 20, 1979 and February 28, 1979 (Patients Morris, Baker, Knauf and Siedentop). Result of appeal for reconsideration: previous denial was upheld in all four cases. Reason for denial was identical in all cases: "Reason: No evidence of vertebral artery obstruction exists; x-rays reviewed by two panels of PSRO expert physicians on separate occasions. Both panels agreed there was no vertebral artery obstruction demonstrated." [Exh. A-116, CAR 3601-3603, 10108-10115; Docket #11 & #18]

20. 'Notice of Determination of Violation of Obligation' dated June 26, 1979 from PSRO Area 22 to Dr. Hurvitz alleged that he had violated his obligation under Section 1160(a)(1), 42 USC 1320c-9; on page 5 of the Notice it states: "On April 18, 1979, a team

of physician advisors, acting on behalf of Area 22, reviewed the arch aortograms of 15 patients who had been admitted to Century City Hospital for vertebral artery surgery performed by Dr. Hurvitz. In each instance, the aortogram failed to reveal findings warranting the surgical procedure." [Exh. R-4, CAR 6464-6479, Excerpts - #10].

21. In a letter dated July 29, 1980, Secretary, through HCFA, notified Dr. Hurvitz that she would exclude all items and services furnished by him from reimbursement under Medicare Program for two years effective August 13, 1980, under Section 1862(D)(1)(c), 42 USC 1395y. Reasons for exclusion are stated on page 9 of the letter: "The standard that a valid obstructuion must be documented by radiologic evidence in order for surgery to be determined to be medically necessary is not an unreasonable one...The record also reveals that he is committed to continuing to perform this procedure." [Exh.R-7, CAR 6482; Appendix hereto, p.A128]

22. One of the Medicare patients herein

involved, Gail Morris, appealed denial of Medicare payment by PSRO Area 22 for her hospitalization, angiography and vertebral artery surgery in February, 1979, at Century City Hospital. A hearing was held before ALJ Schiff, who issued a decision on January 8, 1980, stating that Ms. Morris' hospitalization and vertebral artery surgery were reasonable and necessary [CAR 10987-10992, Exh. AC-3, Docket #18].

23. In appellate hearing of Medicare Patient Leo Stewart, ALJ Mallory C. Walker issued a decision on Oct. 31, 1976 [Exh.A-142, CAR 10180-10184, Docket #18] which states: "Vertebral artery surgery was performed on July 21, 1976, by S. Allan Hurvitz, MD, MD, and was reasonable and medically necessary...A letter from the beneficiary's treating physician, S. Allan Hurvitz, MD, a highly qualified thoracic and cardiovascular surgeon, is in the file."

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VII. Reasons for Granting Writ

1. REGARDLESS OF WHETHER OR NOT DR. HURVITZ RAISED OR PRESERVED HIS CONSTITUTIONAL CLAIMS IN ADMINISTRATIVE PROCEEDINGS, REVIEWING COURT HAS DISCRETION TO CONSIDER CONSTITUTIONAL ISSUES, AND IN THE CIRCUMSTANCES DISTRICT AND APPELLATE COURTS SHOULD HAVE DONE SO.

District and Appellate Courts refused to consider and decide constitutional claims which Dr. Hurvitz raised: (1) that basis of his sanction violated his Due Process rights and (2) whether his published and non-published ideas of diagnosis and surgical treatment of vertebral artery obstruction (VAO) are protected by First Amendment guarantee of freedom of speech. District Court based its refusal on grounds (1) that Due Process claim, though admittedly made before ALJ, was not preserved before Appeals Council, and (2) that freedom of speech claim was raised for first time before district court [SUFCL, Appendix hereto A21-22]. Said Courts also refused to consider

constitutionality of 42 USC 1395y, Section 1862(D)(1)(c).

Numerous opinions of Ninth Circuit Court of Appeals establish principle that Court has discretion to review issue raised for first time on appeal. In Yuckert v. Heckler, 774 F.2d 1365, 1367 (9th Cir. 1986), reversed on other grounds, Bowen v. Yuckert, ___U.S.___, 96 L.Ed.2d 119, 107 S.Ct. 2287 (1987), Court described factors which justify exercise of this discretion: "Generally, we will not consider an argument on appeal if the parties failed to raise it below. [Citations.] Nevertheless, we recognize an exception to this rule where the issue is purely one of law that is both central to the case and important to the public. [Citations.] Here, our consideration of the issue will not require the parties to develop new facts; moreover, the validity of the [social security] regulation presents a significant question of general impact. [Citation.] Thus, we exercise our discretion to consider the issue in spite of Yuckert's failure to

raise it in the district court. [Citation.]" Upon considering validity of regulation challenged in Yuckert, Court found the regulation invalid.

Court described these factors slightly differently in Quinn v. Robinson, 783 F.2d 776, 814 (9th Cir. 1986), cert. denied, ___U.S.___, 93 L.Ed.2d 247, 107 S.Ct. 271 (1987): "As a general rule, 'a federal appellate court does not consider an issue not passed upon below.' [Citation.] But this rule is not inflexible. [Citation.] We have discretion to decide whether to address an issue that the district did not reach if the question is a purely legal one and the record has been fully developed prior to appeal; in deciding whether to exercise this discretion we should consider whether the resolution of the issue is clear and whether injustice might otherwise result. [Citation.]" In Quinn, Government, as Appellee, raised issue for first time on appeal but did not brief it. Appellant objected on ground that additional time

required for both parties to brief issue would prejudice him, in that he was in custody. In these circumstances Quinn court declined to consider issue. Court has sometimes declined to consider newly raised issue absent an excuse for failure to raise it below. See, e.g., Unioil, Inc. v. E. F. Hutton, & Co., 809 F.2d 548, 558 (9th Cir. 1986) (since no manifest injustice resulted, court denied review for failure to explain why issue not previously raised). In present case, all factors mentioned by Yuckert, Quinn and Unioil courts are present.

A. Dr. Hurvitz's Constitutional Claims Are Purely Issues Of Law

Issue of whether Due Process prohibits Secretary from excluding Dr. Hurvitz from participating in Medicare Program under regulation which permits sanction based on letter-recommendation (lacking specific information) from PSRO for alleged failure to comply with one Condition of Transmittal (listing four vague Conditions for Medicare payment) which was never published in Federal

Register is purely one of law. Whether Dr. Hurvitz's medical ideas and methods, published and unpublished, are protected by First Amendment guarantee of free speech is also purely issue of law.

B. The Record In This Case Has Been Fully Developed

Facts in this case have been fully developed. Administrative hearing consumed 43 days, generating transcript of 10,992 pages. In Order issued on February 5, 1982 [Exh. C-10, Excerpts #16], ALJ found, and Secretary does not dispute, that Transmittal 715, on which Dr. Hurvitz's sanction was based, has never been published in Federal Register.

Dr. Hurvitz did raise Due Process issue before ALJ, as disclosed by February 5, 1982 Order of ALJ Schiff. Failure of Appeals Council to concur with ALJ's opinion in his Order of February 5, 1982, resulted from "loss" of that Order from Record. Dr. Hurvitz did raise Due Process issues before Appeals Council in his Brief in Support of

Request for Review of Hearing Decision [CAR 194, 197-199, 245-276]. Both parties filed extensive briefs before Appeals Council and in District Court. No other fact-finding would have been necessary to enable District and Appellate Courts to rule on constitutional issues. In SUFCL [Appendix hereto A32], District Court states: "It is true, that the ALJ's order of February 5, 1982 (see plaintiff's Memorandum, Exhibit I) is not included in the record."

C. Dr. Hurvitz's Constitutional Claims Are Central To Case And Important To Public

Issue of whether Secretary violated Dr. Hurvitz's Due Process rights by excluding him from Medicare Program for alleged violation of Transmittal which was never published in Federal Register is central to his appeal. If his Due Process rights were violated, his exclusion cannot stand and summary judgment and affirming appellate court judgment must be reversed. Dr. Hurvitz's claim that his exclusion from Medicare Program was an atttempt to control expression of his ideas

and methods concerning medical diagnosis and treatment is also central to his case.

These issues are important to public as well as to Dr. Hurvitz. Medicare Program affects large portion of population who depend on it for payment of medical expenses, and affects many physicians and other providers. Validity of Secretary's Regulation and standards for excluding providers from Medicare Program is important to public as well as central to this case.

D. Failure To Consider Dr. Hurvitz's Constitutional Claims Would Result In Injustice

Manifest injustice would result if Dr. Hurvitz's Due Process and First Amendment claims were not considered. Since 1980 he has been excluded from participation in Medicare Program and thus deprived of substantial portion of his livelihood. Exclusion was based on vague standards never published in Federal Register and accordingly were invalid as Regulation which Secretary could enforce, particularly in so drastic a

manner. In 1986, Assistant U.S. Attorney Ian Fan rejected Dr. Hurvitz's Settlement Offer based on Secretary reinstating him in Medicare Program. Probability that Dr. Hurvitz was excluded from Medicare Program because of medical ideas, beliefs and actions unpopular with Secretary or her agents, is repugnant to constitutional guarantee of freedom of speech and expression of ideas. Grave injustice would result if this Court failed to review these claims.

There were no facts justifying District and Appellate Courts' refusal to consider Dr. Hurvitz's Due Process and First Amendment issues. In that summary judgment is a drastic remedy which deprives litigant of right to trial on merits, District Court abused its discretion in refusing to consider and rule on Dr. Hurvitz's constitutional claims. Court of Appeals similarly abused its discretion by refusing to consider and rule on those same Constitutional claims. Similarly, all factors which ordinarily justify exercise of reviewing court's

discretion to consider issue not raised below have been met here, and this Court is respectfully requested to consider Dr. Hurvitz's constitutional claims.

2. SANCTION IMPOSED BY DEFENDANT AGAINST DR. HURVITZ WAS UNREASONABLE, UNWARRANTED, UNLAWFUL AND ABUSE OF DISCRETION.

Issue for decision at Hearing before ALJ, as stated in Prehearing Conference Order, was "whether or not it was a reasonable exercise of discretion of Secretary to determine on July 29, 1980, that all items and services provided by Appellant should be excluded....for a period of two years from coverage in the Federal Medicare Program" [Exh.C-3, CAR 10770-73, Excerpts #15]. See "Conclusion", infra, pages 46-47.

3. THERE WAS VIOLATION OF DR. HURVITZ'S RIGHT OF DUE PROCESS UNDER FIFTH AND FOURTEENTH AMENDMENTS BY SECRETARY'S DECISION EXCLUDING ALL ITEMS AND SERVICES RENDERED BY HIM FROM REIMBURSEMENT UNDER MEDICARE FOR TWO YEARS UNDER 42 USC 1395y, SECTION 1862(D)(1)(c), BASED ON TRANSMITTAL 715, AND

ON ALLEGATION THAT VERTEBRAL ARTERY SURGERIES PERFORMED BY HIM ON 24 PATIENTS WERE UNNECESSARY, SINCE TRANSMITTAL 715 HAS NEVER BEEN PUBLISHED IN FEDERAL REGISTER.

Whether or not 24 patients who had vertebral artery surgery performed by Dr. Hurvitz required surgery must, of necessity, be a "scientific fact". Medical opinions vary. What one doctor may find necessary, another doctor may find unnecessary. Under our Constitutional framework, we have laws that determine standards. Due process means that before an individual may be penalized for his actions, he has a right to have a law exist which gives him notice of prohibited conduct. Absence of such notice means lack of due process. There is no Federal Regulation or Federal law setting forth standards for indications and performance of vertebral artery surgery. Dr. Hurvitz was "tried and convicted" of violating rule of law which does not exist. Medical opinions from Medicare or from any physician are not and cannot be laws. Legal rights cannot be

[illegible]

[illegible]

djudicated upon medical opinions.

ransmittal 715 is a medical opinion, is not Federal Regulation and has no validity as asis for imposition of sanction on a hysician.

U.S.C., Title 5, Section 558 states: 'Imposition of sanctions: (b) A sanction may ot be imposed or a substantive rule or order ssued except within jurisdiction delegated o the agency and as authorized by law."

Regarding force and effect of matter not ublished in Federal Register, court ruled hat "no administrative action taken pursuant o unpublished procedures can be allowed to tand against a person adversely affected hereby." Northern California Power Agency . Morton, D.C.D.C. 1975, 396 F.Supp. 1187, ffirmed 539 F.2d 243, 176 U.S.App.D.C. 241. ourt ruled that Navy port regulation not ublished in Federal Register was not ffective. In re Pacific Far East Line, nc., D.C.Cal. 1970, 314 F.Supp. 1339, ffirmed 472 F.2d 1382.

Exhibit C-10 [Excerpts, #16] is missing

rom Record, and is an "Order Amending esults fo Prehearing Conference" signed by LJ Schiff which states: "Appellant's motion as granted in part because Transmittal 715 as not been filed and published in the 'ederal Register."

Medicare Bulletin No. 146 [Exh.A-153(4), AR 10333-34, Excerpts #3] was unilaterally ssued by Blue Cross of Southern California n 1976, stating that vertebral artery surgery was *not* covered by Medicare. Instead of admitting to an error and ordering its agent, Blue Cross, to withdraw Bulletin #146, Medicare "replaced" Bulletin #146 with Transmittal 715, which declares that vertebral artery surgery *is* covered by Medicare. Medicare has *not* issued a Transmittal for any of the other thousands of surgical operations covered by Medicare.

4. IMPOSITION OF SANCTION ON DR. HURVITZ BY SECRETARY UNDER *42 USC 1395y, SECTION 1862(D)(1)(c)* VIOLATED HIS DUE PROCESS RIGHTS, SINCE SAID REGULATION FAILS TO PROVIDE AN OBJECTIVE, FAIR PROCEDURE FOR

DETERMINING WHETHER VERTEBRAL ARTERY SURGERIES WERE NECESSARY, AND SHOULD BE RULED INVALID AND UNCONSTITUTIONAL.

Said Regulation fails to require Secretary to adhere to any objective standard. Under said Regulation, all Secretary had to do to sanction Dr. Hurvitz was to consider one report from PSRO 22 (lacking specific information) recommending sanction. PSRO 22 was run by group of doctors who disagreed with Dr. Hurvitz's ideas and methods of diagnosis and surgical treatment of vertebral artery obstruction ("VAO"), who were in economic and scientific competition with him, who were on Staff of Saint John's Hospital, Santa Monica, CA, and who had excluded him from that hospital's staff beginning in 1964.

Conflict of interest existed on part of PSRO's President and Medical Director Edwin C. Butler, MD, member of staff at St. John's Hospital [CAR 929, 931; Docket #9], who testified that he is not an expert in diagnosis of vertebral artery disease or

surgery [CAR 988, lines 17-23; Docket #9].

Conflict of interest existed on part of Roscoe Webb, MD, member of PSRO and its consultant on vertebral artery surgery, who had never done surgery on a vertebral artery [CAR 1900, lines 12-17; Docket #9], on staff at St. John's Hospital [CAR 1758, line 20; Docket #9] having played a major role in excluding Dr. Hurvitz from staff of St. John's Hospital from 1964 to 1974. [Memorandum 104-5, Docket #49]

5. DR. HURVITZ'S RIGHT TO FREEDOM OF SPEECH WAS VIOLATED BY SECRETARY'S DECISION EXCLUDING ALL ITEMS AND SERVICES RENDERED BY HIM FROM REIMBURSEMENT UNDER MEDICARE PROGRAM FOR TWO YEARS BASED ON ALLEGATION THAT 24 VERTEBRAL ARTERY SURGERIES PERFORMED BY HIM WERE UNNECESSARY, AND HIS PUBLISHED AND NON-PUBLISHED IDEAS OF DIAGNOSIS OF VAO AND TREATMENT OF SYMPTOMATIC VAO WITH VERTEBRAL ARTERY SURGERY ARE PROTECTED BY FREEDOM OF SPEECH CLAUSE IN FIRST AMENDMENT.

See U.S.C., Title 5, Section 558, supra.

See Dr. Hurvitz's published articles on vertebral artery surgery in evidence [CAR 9869-9875, 9908-9914, 9991-9994; Docket #17].

In Goldstein v. Town of Nantucket, court ruled that, by its terms, First Amendment forbids infringement of right of free speech and this constitutional protection of free speech, moreover, applies broadly to various forms of expression, including litery, artistic, political and scientific [477 F.Supp. 606 D.C.Mass. 1979]. In Aumiller v. Univ. of Delaware, court ruled that fundamental purposes of First Amendment is to protect from Government infringement of free expression of controversial and unpopular ideas [434 F.Supp. 1273, D.C.Del. 1977].

6. THERE WAS ABUSE OF DISCRETION IN THAT PSRO 22 HAD NO AUTHORITY TO REVIEW PART B SERVICES OF PHYSICIANS, INCLUDING VERTEBRAL ARTERY SURGERY DONE BY DR. HURVITZ, AND HAD NO AUTHORITY TO WITHDRAW WAIVER OF LIABILITY FOR VERTEBRAL ARTERY SURGERY FROM HIM.

See Part VI, Paragraphs 16-17, pages 14-15, supra. PSRO 22 had no legal authority

to review actual vertebral artery surgery performed by Dr. Hurvitz. This is proven by letter in evidence dated April 13, 1979, from Wayne Moon of Medicare's HCFA, Exh.A-45, CAR 8450-1, Excerpts #9: "To date, neither Area 22 PSRO nor any other California PSRO has received approval to review physician inpatient hospital services under Part B of the Medicare Program."

"Questions Presented" 7 & 8, pp. iii-iv, supra, should be presented and read here as positive statements.

9. FINDING AND CONCLUSION OF ALJ IN HIS DECISION AND IN FINAL DECISION OF SECRETARY THAT DR. HURVITZ MET AND COMPLIED WITH REQUIREMENT OF CONDITION 3 OF TRANSMITTAL 715 COMPLETELY EXONERATES HIM [CAR 553, Appendix hereto A104-106], SINCE SECRETARY'S INITIAL DECISION TO EXCLUDE HIM FROM MEDICARE PROGRAM WAS ISSUED FOR ONE SPECIFIC STATED REASON - SECRETARY'S INITIAL ALLEGATION THAT HE FAILED TO MEET CONDITION 3 OF TRANSMITTAL 715 [Exh.R-7, CAR 6482, Appendix hereto A128]; CONDITION 3 REQUIRES PRESENCE OF RADIOGRAPHIC

EVIDENCE OF VALID VERTEBRAL ARTERY OBSTRUCTION IN PATIENTS ON WHOM VERTEBRAL ARTERY SURGERY IS PERFORMED TO QUALIFY FOR MEDICARE PAYMENT [Exhs.R-1 & R-2, CAR 6451, 6455; Excerpts #6 & #7].

ALJ states: "Therefore, giving Dr. Hurvitz the benefit of the doubt and relying on his reasonable, although perhaps mistaken belief that the x-rays show an obstruction, the undersigned cannot conclude otherwise than that the Government did not show by a preponderance of the evidence that Dr. Hurvitz's x-rays did not indicate, at least in some good faith and reasonable way to Dr. Hurvitz, the presence of a valid vertebral artery obstruction. Thus, although it is said that pictures do not lie, these pictures equivocate because, based on the conflicting interpretations superimposed on them by the experts, they do not unambiguously show that there is no obstruction of these 24 patients' vertebral arteries. For that reason, Dr, Hurvitz's reasonable, though perhaps misplaced, interpretation must prevail. His

good faith belief that the x-rays show an obstruction, and his good faith reliance on the opinion of his radiologist, Dr. Burrows, that the x-rays show 'abnormalities', are held to satisfy the third criteria that there be radiographic evidence of a valid vertebral artry obstruction before surgery on those arteries will be considered medically reasonable and necessary" [CAR 553, Appendix hereto A104-106].

10. ALJ'S DECISION AND FINAL DECISION OF SECRETARY WERE IN ERROR, SINCE THEY FOUND THAT DR. HURVITZ FAILED TO COMPLY WITH CONDITION 1 OF TRANSMITTAL 715 (symptoms of vertebral artery obstruction exist) AND WITH CONDITION 2 OF TRANSMITTAL 715 (other causes have been considered and ruled out); RECORD COMPELLS FINDING THAT HE COMPLIED WITH CONDITIONS 1 AND 2 OF, SINCE HE SUBMITTED TO APPEALS COUNCIL COMPREHENSIVE DISCUSSION OF HOSPITAL CHART OF ALL 24 PATIENTS SHOWING THAT HE MET SAID CONDITIONS [CAR 306-495; Appendix B to Petition for Rehearing, Appellate Court].

"Comprehensive Discussions" in evidence tabulate and document evidence in hospital charts that all 24 patients had "symptoms of vertebral artery obstruction" (Condition 1) designated in Transmittal 715 and that all 24 patients had "other causes considered and ruled out" (Condition 2) as designated in Transmittal 715.

"Questions Presented" 11 through 37, pp. iv-xvi, supra, should all be presented and read here as positive statements.

CAR shows that ALJ hearing was conducted in adversary setting; this issue and issue of speedy trial were raised below and exhausted. "Hearings under the Social Security Act are not adversary procedures"; Social Security Act216(i), 223 (c,d), (d)(5) as amended 29 USCA 416 (i), 423(c,d)(d)(5); Gold v. Secretary of Health, Education & Welfare, 463 F.2d 38 (2nd Cir. 1972); Hennig v. Gardner, 276 F.Supp. 622 (D.C. Texas 1976). District and Appellate Courts overlooked or misapprehended a number of points of law and fact. Presiding Appellate Court Judge Alfred

T. Goodwin, stated on May 8, 1988 at hearing and oral argument that he did NOT have entire Record of this case for review.

Conclusion of Court of Appeals that Dr. Hurvitz performed vertebral artery surgeries substantially in excess of his patients' needs is incorrect, unreasonable and irrational. Objective medical facts in evidence in Record in hospital charts of all patients show overwhelming evidence that all patients had both objective and subjective improvement after their surgeries, with partial restoration of lost neurologic function, and that vertebral artery obstruction was found at surgery in all patients and described in Operative Reports [Exhs. A-58 to A-81, CAR 8469-9847; Appendix A, Petition for Rehearing, Appellate Court].

Since surgeries performed by Dr. Hurvitz caused objective improvement in all patients, and since vertebral artery obstruction was found at surgery and was described in detail in all Operative Reports, a reasonable and rational mind can only conclude that the

surgeries were medically necessary and reasonable, and that diagnosis of VAO was correct; conclusion to contrary is irrational. There is no conflicting evidence regarding VAO found at surgery.

For Appellate Court's convenience, Discharge Summary, History and Physical Examination, Physical Therapist's Report of patient's pre-operative and post-operative grip testing, and Operative Report from each patient's hospital chart [CAR 8469-9847] were attached as Appendix A to Petition for Rehearing.

Dr. Hurvitz asks that this Court focus its attention on "Questions Presented", points 20, 21 and 24 , supra, which follow as positive statements:

20. DECISIONS OF ALJ, APPEALS COUNCIL AND FINAL DECISION OF SECRETARY FAILED TO TAKE ALL EVIDENCE INTO ACCOUNT AND REJECTED EVIDENCE THAT CONFLICTS WITH THEIR ADVERSE FINDINGS OF FACT, REGARDING THEIR FINDINGS THAT DR. HURVITZ FAILED TO COMPLY WITH CONDITIONS 1 & 2 OF TRANSMITTAL 715 AND THAT

HIS TWO YEAR SANCTION WAS REASONABLE.

21. ALJ, APPEALS COUNCIL AND SECRETARY DISREGARDED AND REJECTED IRREFUTABLE, OVERWHELMING EVIDENCE CLEARLY RECORDED IN OPERATIVE REPORTS THAT SIGNIFICANT PARTIAL OBSTRUCTION OF OPERATED VERTEBRAL ARTERY EXISTED AND WAS FOUND AT SURGICAL OPERATION IN ALL 24 PATIENTS.

24. ALJ, APPEALS AND SECRETARY DISREGARDED AND REJECTED OVERWHELMING EVIDENCE THAT EACH PATIENT HAD OBJECTIVE POST-OPERATIVE IMPROVEMENT RECORDED IN HIS OR HER HOSPITAL CHART AND DESCRIBED IN TYPED AND SIGNED 'DISCHARGE SUMMARY', WHICH FURTHER CONFIRMED DIAGNOSIS OF VAO.

ALJ, Appeals Council, and Secretary irrationally refused to consider facts in evidence that all patients had objective and subjective improvement after surgery, and that VAO was found at surgery; they based their conclusion that the surgeries were not reasonable and necessary ONLY on their adverse findings that Dr. Hurvitz did not met Conditions 1 and 2 of Transmittal 715

(absence of "drop attack" in 19 of the 24 patients).

HCFA's witnesses testified on "ADMISSION RECORDS", HCFA's Exhibits R-8 to R-27 [CAR 6474-6856], which contain only parts of 20 patients' hospital charts; HCFA's witnesses failed to testify regarding the undisputable operative finding of vertebral artery obstruction - THERE IS NO CONFLICTING EVIDENCE IN THE RECORD ON THIS DECISIVE POINT (VAO). Dr. Hurvitz entered into evidence complete hospital chart records of all patients, Exhs. A-58 to A-81 [CAR 8469-9847], which were not reviewed by HCFA's witnesses.

Transmittal 715 [Excerpts #6, CAR 6451] lists symptoms of VAO: "Obstructions which block the flow of blood through the vertebral artery can cause vertigo, visual or speech defects, ataxia, mental confusion, or stroke. These symptoms in patients result from reduction in blood flow to the brain and range from symptoms of transient basilar ischemia to mental deterioration and completed stroke." Note that Transmittal 715

does NOT list "drop attack" as a symptom of VAO.

Assistant U.S. Attorney Ian Fan stated in Secretary's Response Brief and in oral argument before Court of Appeals that ALJ, Appeals Council and Secretary concluded that Dr. Hurvitz failed to meet Condition 1 of Transmittal 715 (that "symptoms of vertebral artery obstruction exist"), since all patients did not have a "drop attack", and that a "drop attack" was primary consideration (sine qua non) in finding that vertebral artery surgeries performed by Dr. Hurvitz were not reasonable and necessary. Since no Government witness testified regarding the "drop attack", how could ALJ and Appeals Council find Government's witnesses more credible regarding true facts of "drop attack"? ALJ and Secretary abused their discretion by decreeing that a patient could not have VAO without a having had a "drop attack".

In expressing erroneous view regarding "drop attack", ALJ quoted Dr. Hurvitz's

witness, Dr. Adam Wesolowski, and Dr. Hurvitz himself, and then arrived at his erroneous conclusion. ALJ states [CAR 546, Appendix hereto A89-90]: "Dr. Hurvitz himself testified that the two symptoms which distinguish vertebral artery obstruction from any other cause, especially multiple sclerosis, are drop attacks and transient ischemic attacks (TR: 185-186, red). Dr. Hurvitz's witness, Dr. Wesolowski, testified that he considers the "drop attack" to be "pathognomonic" for vertebral artery disease, in other words, a finding of a drop attack "makes" the diagnosis of vertebral artery obstruction (TR: 2255). He knew of no other condition besides vertebral artery obstruction that produces the drop attack syndrome (TR: 2255). A review of the evidence and the available medical literature on the subject substantiates Dr. Hurvitz's and Dr. Wesolowski's testimony: vertebral artery disease is characterized by symptoms of "drop attacks", that is, a sudden collapse of the legs due to muscle weakness without

loss of consciousness which lasts only briefly....the so called "drop attack" is the sine qua non of the malady...Indeed, out of 24 cases, fully 19 make no mention of drop attacks."

Dr. Hurvitz and his witness, Dr. Wesolowski, both testified that 5 of 24 patients had written descriptions in their hospital charts of "drop attacks". Drs. Wesolowski and Hurvitz did NOT testify that "vertebral artery disease is characterized by symptoms of 'drop attacks'", as stated by ALJ in his decision, supra. Dr. Wesolowski testified that "vertebral artery obstruction is the only disease that causes drop attacks, but a drop attack is not required for the diagnosis of vertebral artery obstruction" [CAR 3271]. ALJ's statement that "vertebral artery disease is characterized by symptoms of 'drop attacks'", is ABSOLUTELY FALSE. Medical article in evidence [Exhibit A-20, CAR 8223, attached to Petition for Rehearing before Appellate Court as Exhibit I], giving statistic of frequency of occurrence of "drop

attack" in VAO, states that 5.5% of patients with VAO have had "drop attacks". ALJ abused his discretion by inventing his own statistic (100%) regarding frequency of "drop attacks" in patients with VAO, and thereby found that Dr. Hurvitz did not meet Condition 1 of Transmittal 715. This false decree by ALJ that a "drop attack" is sine qua non of vertebral artery surgery was adopted by Appeals Council, which became final decision of Secretary. In other words, Secretary's final decision is based on alleged "substantial evidence" that 19 of the 24 patients did not have "drop attacks".

VIII. CONCLUSION

All 37 "Questions Presented", supra, were presented in Opening Briefs by Dr. Hurvitz filed in District and Appellate Courts. Appeals Council states it "recognizes that the medical criteria and specific indications for surgical procedures in vertebral artery lesions are still undergoing evaluation and this is a field without definitive answers" [Appendix hereto

A50]; this statement exonerates Dr. Hurvitz. District's Court's ruling (affirmed by Appellate Court) in Point 5 of its Conclusions of Law that PSRO Area 22 had authority to review vertebral artery surgery and to recommend exclusion of Dr. Hurvitz under Transmittal 688(715) [Appendix hereto A20], violates Dr. Hurvitz's Due Process guarentees and must be reversed.

Dr. Hurvitz's Constitutional claims are purely issues of law. Due Process clearly prohibited Secretary from excluding Dr. Hurvitz from participating in Medicare Program under a Regulation which permits sanction based on letter-recommendation from PSRO (lacking specific information) for alleged failure to comply with one Condition of Transmittal (listing four vague Conditions to qualify for payment by Medicare) which was never published in Federal Register. Adverse findings of Secretary's final decision are not supported by substantial evidence; her arguments lack merit, and there is no genuine issue of material fact.

Pursuant to Constitutional law and to Court's ruling in Blalock v. Richardson , 483 F.2d 773 (CA4 1972) since objective medical facts in evidence in the 24 hospital charts, Exhibits A-58 through A-81 [CAR 8469-9847], prove overwhelmingly that vertebral artery obstruction was found at surgery in all 24 patients and that all patients had good surgical results with objective improvement after surgery, then all 24 vertebral artery surgeries performed by Dr. Hurvitz must be ruled reasonable and medically necessary. There is no conflicting evidence in Record regarding undisputable finding and existence of vertebral artery obstruction described in Operative Reports of all patients; HCFA's witnesses failed to testify on this decisive issue. Sanction imposed on him by Secretary must be ruled unreasonable, illegal, unconstitutional and be nullified. Dr. Hurvitz is entitled to judgment in his favor as matter of law and fact - Court of Appeals' decision must be overturned.

For these reasons, a writ of certiorari

should issue to review judgment and opinion of Court of Appeals. If writ of certiorari is granted, then Petitioner requests that this Court reverse Appellate Court's judgment, nullify Petitioner's exclusion from participation in Medicare Reimbursement Program, and order Secretary to reinstate Petitioner's eligbility to participate in Medicare Reimbursement Program, so that justice and the law and spirit of Constitution shall prevail.

Respectfully submitted,

Date: Sept. 29, 1988 S Allan Hurvitz

S. ALLAN HURVITZ, MD
Petitioner, In Pro Se

APPENDIX

OPINION AND JUDGMENT OF NINTH CIRCUIT COURT OF APPEALS

NOT FOR PUBLICATION

IN THE UNITED STATES COURT OF APPEALS
FOR THE NINTH DISTRICT

S. ALLAN HURVITZ,
Plaintiff-Appellant,
v.
MARGARET M. HECKLER, SECRETARY OF
HEALTH & HUMAN SERVICES,
Defendant-Appellee.

No. 87-5682
D.C. No. CV 85-1590 JSL
MEMORANDUM^

Appeal from the United States District Court
for the Central District of California
J. Spencer Letts, District Judge, Presiding
Argued and Submitted May 5, 1988
Pasadena, California
Filed May 23, 1988

Before: GOODWIN and HALL, Circuit Judges,
and PANNER,^^^ District Judge.

Hurvitz appeals from the decision of the district court affirming the final decision of the Secretary to exclude him from being

reimbursed by Medicare for the surgeries he performs. Hurvitz argues there is insufficiency evidence to support the Secretary's decision and raises numerous other claims. We Affirm.

The Secretary excluded Hurvitz from future reimbursement for his services because he had performed surgeries that were substantially in excess of his patients' needs. 42 U.S.C. Section 1395y(d)(1)(C), (d)(2) (1982). We review this decision of the Secretary for substantial evidence. 42 U.S.C. Subsection 1395y(d)(3), 405(g) (1982). We must affirm if there is relevant evidence that a reasonable mind might accept as adequate to support a conclusion, even if it is possible to draw two different conclusions from the evidence. St. Elizabeth Community Hospital v. Heckler, 745 F.2d 587, 592 (9th Cir. 1984).

Hurvitz primarily argues that the ALJ improperly weighed conflicting evidence. However, both the ALJ and the Appeals Council found the Government's witnesses more

credible. Determining questions of credibility and resolving conflicts in the evidence are functijons solely of the Secretary. Sample v. Schweiker, 694 F.2d 639, 642 (9th Cir. 1982). After carefully reviewing the record, we hold there is substantial evidence to support the decision of the Secretary.

Hurvitz's other claims are meritless.

AFFIRMED.

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*This disposition is not appropriate for publication and may not be cited to or by the courts of this circuit except as provided by Ninth Circuit Rule 36-3.

***Honorable Owen M. Panner, Chief Judge, United States District Court for the District of Oregon, sitting by designation.

SUMMARY JUDGMENT OF DISTRICT COURT

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UNITED STATES DISTRICT COURT

FOR THE CENTRAL DISTRICT OF CALIFORNIA

S. ALLAN HURVITZ, M.D.,

Plaintiff,

v.

OTIS T. BOWEN, Secretary
of Health and Human Services, 1 /

Defendant.

NO. CV 85-1590-JSL

JUDGMENT (Proposed)

Date: February 9, 1987

Time: 3:30 p.m.

The parties' cross-motions for summary

judgment came on for hearing on February 9, 1987, before the Honorable J. Spencer Letts, United States District Judge. Defendant was represented by Ian Fan, Asssistant United States Attorney. Plaintiff represented himself in propia persona .

After consideration of the pleadings and the argument of the parties, IT IS ORDERED, ADJUDGED, and DECREED, in conjunction with the Statement of Uncontroverted Facts and Conclusions of Law which are being currently filed, that defendant's motion is granted and plaintiff's motion is denied, and judgment is entered in favor of efendant.

DATED: Feb. 24, 1987

J. SPENCER LETTS

UNITED STATES DISTRICT JUDGE

PRESENTED BY:

ROBERT C. BONNER

United States Attorney

FREDERICK M. BROSIO, JR.

Assistant United States Attorney

Chief, Civil Division

IAN FAN

Assistant United States Attorney

Attorneys for Defendant

DISTRICT COURT'S STATEMENT OF UNCONTROVERTED FACTS AND CONCLUSIONS OF LAW

Entered With Summary Judgment

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UNITED STATES DISTRICT COURT
FOR THE CENTRAL DISTRICT OF CALIFORNIA

S. ALLAN HURVITZ, M.D.,
Plaintiff,
v.
OTIS T. BOWEN, Secretary
of Health and Human Services, 1 /
Defendant.

NO. CV 85-1590-JSL

STATEMENT OF UNCONTROVERTED
FACTS AND CONCLUSIONS OF LAW

Date: February 9, 1987
Time: 3:30 p.m.

STATEMENTS OF UNCONTROVERTED FACTS

1. On September 1, 1978, the Medicare Bureau adopted Transmittal Nos. 688 and 715. Transmittal No. 715 concerned Part A of the Medicare Act. Transmittal 688 concerned Part B of the Medicare Act. Both transmittals dealt with vertebral artery surgery, which is used to relieve obstruction which block the blood flow through the vertebral artery. Five types of surgical procedures are used to relieve such obstructions, including arteriolysis. Such procedures can be medically reasonable and necessary, but only if each of four conditions are met: (1) symptoms of vertebral artery obstruction exist; (2) other causes have been considered and ruled out; (3) there is radiographic evidence of a valid vertebral artery obstruction; and (4) contraindications to the procedure do not exist. In addition, arteriolysis "is only rarely considered to be medically necessary and easonable for the individual patient."

2. After the adoption of Transmittal

Nos. 688 and 715, plaintiff continued to operate on patients for alleged verebral artery obstruction. On February 15, 1979, the local Professional Standards Review Organization ("PSRO") informed Century City Hospital, the hospital to which plaintiff admitted these patients and where the procedures took place, that it had voted to withdraw plaintiff's waiver of liability status, because a study of six patients of plaintiff's patients showed that the four requirements of Transmittal No. 688 had not been met. The PSRO was so notifying Blue Cross, the contractor. In other words, the hospital was being put on notice that it would be liable for future patients of plaintiff if the four requirements were not met. In a followup letter, PSRO explained that if all Medicare guidelines were met, the patient's stay at the hospital would be certified for payment. However, all other cases would be denied.

3. On February 27, 1979, Century City Hospital sent plaintiff a copy of the

February 15, 1979 PSRO letter, and informed him that his patients must henceforth prepay their amount prior to surgery.

4. A PSRO Committee met on March 19, 1979 to review the records of five of plaintiff's patients, all of whom had been admitted to Century City Hospital on or after February 19, 1979. The Committee determined that none of the surgical procedures were deemed reasonable or necessary, and in addition expressed concern regarding general deficiencies, including plaintiff's failure to consult a neurologist and identical diagnoses for each patient.

5. Thereafter, on April 18, 1979, a team of physicians, acting on behalf of the PSRO reviewed arch aortograms of fifteen of plaintiff's patients. In each case, the aortogram failed to reveal findings warranting the surgical procedure. In addition, in many instances the aortograms were of inferior quality.

6. The PSRO wrote plaintiff on April 20, 1979, and informed him that pursuant to

the 100% prepayment review of his patients admitted to Century City Hospital after February 15, 1979 with a diagnosis of vertebral artery insufficiency, certain hospitalizations and stays were not being certified for payment. The PSRO was desirous of meeting with plaintiff on April 27, 1979 to discuss the situation. Plaintiff replied on April 25, 1979 that he would not be able to meet. The PSRO then invited him to a meeting set for May 16, 1979. On May 4, 1979, plaintiff informed the PSRO that he refused to meet with them because they had no authority for Part B determinations. The PSRO then explained on May 10, 1979 that it had the authority under Part A "in order to determine whether hospitalization was medically necessary [and to make that determination] the PSRO had to determine whether the surgery requiring the hospitalization was necessary." Plaintiff never appeared at the May 16, 1979 meeting.

7. By letter dated June 26, 1979, plaintiff was advised that the PSRO

determined on May 21, 1979, that he violated his obligations under 42 U.S.C. Section 1320c-9(a)(1) (1976). Plaintiff was informed of his right to submit a written statement, or to request a meeting with the PSRO. At plaintiff's request, the deadline to request a meeting was extended. Plaintiff was informed that no further extensions were possible. In spite of this, on August 2, 1979, one day before the daedline, plaintiff requested a ninety-day extension, and did not request a meeting.

8. Thus, on August 6, 1979, the PSRO notified the statewide PSR Council pursuant 42 U.S.C. Section 1320c-9(b)(1) (Supp. II 1978) that it determined that plaintiff was in violation of his obligations under 42 U.S.C. Section 1320c-9(a)(1) (1976). On September 10, 1979, the Statewide PSR Council recommended to defendant that sanctions be imposed against plaintiff.

9. On January 15, 1980, plaintiff was informed that defendant proposed to exclude him from the Medicare program for a five year

period. Plaintiff was informed of his right to submit a written statement and to meet with a representative of defendant. Plaintiff requested a conference on February 13, 1980, and on April 29, 1980, a conference was held.

10. On July 29, 1980, plaintiff was notified that effective August 13, 1980, he was excluded from the Medicare program for a two year period. He was informed that after such two year period, he might be eligible for reinstatement, and that he could reapply. He was also informed of his right to request an ALJ hearing. Plaintiff requested a hearing on August 5, 1980.

11. A hearing was held beginning on January 28, 1981, and ending on June 18, 1982. The hearing took approximately forty-three days over that period.

12. On July 13, 1983, the ALJ affirmed defendant's decision. The ALJ found that not all of the four requirements of Transmittal No. 715 were met in each of the twenty-four cases studies.

13. Plaintiff requested Appeals Council review on August 22, 1983. On January 14, 1985, the Appeals Council affirmed. Plaintiff filed this action on March 6, 1985, and seeks reinstatement into the Medicare program.

14. To the extent that any of the following Conclusions are deemed to be uncontroverted facts, they are hereby incorporated into this Statement of Uncontroverted Facts.

CONCLUSIONS OF LAW

1. This Court has jurisdiction over this action.

2. Judicial review over the decision in question is permitted by 42 U.S.C. Section 1395y(d)(3). In turn, such judicial review is pursuant to 42 U.S.C. Section 405(g), under which this Court may only affirm, modify or reverse the decision.

3. In addition, the standard of review is the substantial evidence test. 42 U.S.C. Section 405(g). Substantial evidence is "such relevant evidence as a reasonable mind

might accept as adequate to support a conclusion." Richardson v. Perales, 402 U.S. 389, 401 (1971). The fact that inconsistant conclusions can be drawn does not prevent the Secretary's decision from being supported by substantial evidence. Cranston v. Clark, 767 F.2d 1319, 1312 (9th Cir. 1985).

4. Plaintiff initially challenges the propriety of the sanction. However, the sanction involved, which precluded plaintiff from receiving Medicare reimbursement, is specifically provided for by statute and regulation. The statutory scheme in existence at the time plaintiff was excluded required that the PSRO provisions concerning exclusion be followed. That statutory scheme has been found to be constitutional. Association of Am. Physicians & Surgeons v. Weinberger, 395 F.Supp. 125, 131,40 (N.D. Ill.)(three judge court), aff'd Mem., 423 U.S. 975 (1975). Among other things, the PSRO scheme does not violate the physician's right to practice their professon. Id. at 133. In short, the notion that the PSRO can

recommend exclusion is constitutional.

5. In addition, the PSRO acted within its authority in this instance. Plaintiff argues that the PSRO had no authority under Part B. This is irrelevant, since the PSRO had authority to do what it did under Part A. As noted above, Transmittal No. 715 concerns Part A, and Transmittal No. 688 concerns Part B. The two transmittals are virtually identical.

6. Futhermore, the PSRO had authority to determine under Part A whether hospitalization was medically necessary. To make that determination, it had to decide if the surgery which was the basis for the hospitalization was medically necessary. It also had the statutory responsibility to determine whether medical services provided by physicians in their jurisdiction were medically necessary. 42 U.S.C. Section 1320c-4(a)(1)(A) (Supp. II 1978). In other words, the PSRO had authority to do what it did.

7. Finally, plaintiff's allegations

regarding Dr. Maile is totally irrelevant. As plaintiff himself concedes, Dr. Maile is alleged to have illegally issued Medicare Bulletin 146 on September 22, 1976. However, that buletin had no effect on the present proceeding. The real question concerns the issuance of Transmittal Nos. 688 and 715 on September 1, 1978. Plaintiff has never alleged that Medicare Bulletin 146 was relied upon by the PSRO and the Secretary to exclude, and thus its relevance (as well as plaintiff's intent in raising the issue) is questionable.

8. Plaintiff next argues that due process was violated by virtue of his exclusion based upon transmittals which were never published in the Federal Register. However, plaintiff failed to preserve this issue before the Appeals Council. Since plaintiff failed to raise this issue before the Appeals Council, it cannot be raised now. See, e.g. , Israel v. INS, 710 F.2d 601, 605 (9th Cir. 1983), cert. denied, 465 U.S. 1068 (1984).

9. Plaintiff also alleges violation of his freedom of speech. However, this issue was never raised below at any time, and thus may not be raise here.

10. Plaintiff's claim on the merits challenges the decision excluding him from the Medicare Program. Plaintiff claims that the ALJ's decision as to condition 3 exonerates him; that there is no support for the findings that conditions 1 and 2 were not met; that he did not have adequate notice as to defendant's reliance upon conditions 1 and 2; that the receiving physicians relied upon by defendant were not qualified (and conversely that plaintiff, as treating physician, was entitle to deference); that defendant ignored certain evidence; and that multiple sclerosis was a false issue.

11. Medicare Transmittal No. 715 states that vertebral artery surgery may be considered medically necessary (and therefore reimburseable under Medicare) if four conditions are met: (1) symptoms of vertebral artery obstruction exist; (2) other causes

have been considered and ruled out; (3) there is radiographic evidence of a valid obstruction; and (4) contraindications to the procedure do not exist. CAR 6451. A pre-hearing conference of the parties was held on January 28, 1981, at which time the issue to be resolved was "whether or not the subject vertebral artery surgeons performed by [plaintiff] met those criteria set out in [Medicare Transmittal No. 715] (and were, thus medically necessary)." CAR 10771. By order dated February 5, 1982, an unrelated issue was added. See plaintiff's Memorandum, Exhibit I. It can thus be seen that plaintiff's inadequate notice argument lacks merit. Plaintiff argues that he was not apprised in advanced that conditions 1 and 2 would apply to him. However, as noted above, all the conditions were before the ALJ, and his argument was reached before the hearing began. In addition, the extraordinary length of the hearing provided plaintiff ample time to raise what he perceived to be new issues. Thus, plaintiff was able to raise a new

isssue on February 5, 1982, or over a year after the hearing began..

12. This in turn disposes of plaintiff's argument that the ALJ's finding on condition 3 exonerates him. With respect to condition 3, the ALJ gave plaintiff the benefit of the doubt and found that the Secretary had failed to establish its violation. CAR 553. However, as both the Appeals Council and the ALJ noted, all that was needed was for at least one of the four conditions not to have been met. CAR 23, 555. Since the parties had previously agreed the issue in question was not limited to a particular condition, but instead was whether medical necessarily existed (and therefore whether all four conditions were met), the fact that the ALJ did not find a violation of condition 3 is meaningless if at least one other condition was violated. And noted below, such was the case, and thus plaintiff's exoneration argument must be rejected.

13. Condition one requires that symptoms of vertebral artery obstruction exist. As

the ALJ noted, such symptoms include "drug attacks, dizziness, vertigo, visual defects, speech defects, muscle incoordination, mental confusion, headaches, audible bruits and thrills, vomiting, weakness, deafness, and a diminished pain sensation." CAR 538. At the ALJ hearing, the Secretary presented seven physicians who testified that no symptoms of an obstruction could be deduced from the records. CAR 538-40. Instead, the witnesses for the Secretary found in some of the patients that symptoms of multiple sclerosis existed. CAR 538 (Dr. Thompson); CAR 539 (Dr. Blinderman). On the other hand, plaintiff presented four witnesses, including himself, who testified to the contrary. CAR 540-45. The ALJ resolved the issue in favor of the government. In doing so, the ALJ relied on the testimony of one of the plaintiff's (Dr. Wesolowsky) who testified that "a finding of a drug attack 'makes' the diagnosis of vertebral artery obstruction." CAR 546. The ALJ found the absence of the mention of drug atttacks from the patient

records to e "astonishing," id., and "amounts to substantial evidence against [plaintiff] on this issue." CAR 547. He also found the government's witnesses to be more credible than plaintiff's, noting that one of plaintiff's witnesses "doubted even the existence of multiple sclerosis." CAR 548. Finally, he noted that the transient symptoms exhibited by persons with artery obstruction did not exist in plaintiff's patients, who (with perhaps one exception) exhibit chronic symptoms. Id.

14. Before the Appeals Council, plaintiff initially challenged the qualifications of the Secretary's witnesses. However, the Appeals Council noted that vertebral artery surgry was not widely performed, and that "[a]lthough [the Secretary's] witnesses have never performed vertebral artery surgery, their medical expertise in the fields of neurology and thoracic and vascular surgery certainly provides a basis for their testimony as symptoms associated with vertebral artery

surgery insufficiency and whether other neurologic cuases have been eliminated." CAR 19 (emphasis in original). The Appeals Council also placed great emphasis on the lack of drop attacks, id., and stated that "it was incumbent on [plaintiff] to establish the existence of [vertebral artery obstruction] by eliminating other causes for the [patient's] symptoms..." such as multiple sclerosis. CAR 20. The Secretary presented a "strong case" for the diagnosis of multiple sclerosis, "yet [plaintiff] failed to either refer these patients to a neurologist for consultation prior to surgery or obtain the neurological record and in some cases complete neurological workups (e.g. Mayo Clinic) which had been performed." Id.

15. It can thus be seen that the findings as to condition 1 was supported by substantial evidence. It is the role of the ALJ to judge credibility. Sample v. Schweiker, 694 F.2d 639, 642 (9th Cir. 1982). In this case, the ALJ specifically found the Secretary's witnesses to be more credible,

CAR 548, and that finding was adopted by the Appeals Council. CAR 19. The fact that inconsistent conclusions can be drawn from the record does not prevent the Secretary's decision from being supported by substantial evidence. Cranston, 767 F.2d at 1321. In addition, the ALJ's credibility determination is accorded special deference. Howard v. Heckler, 594 F. Supp. 457, 463 (C.D. Cal. 1984), rev'd on othr grounds, 782 F.2d 1484 (9th Cir. 1986). Finally, the evidence relied upon by the ALJ, namely the evidence of the Secretary's witnesses, was adequate to support the conclusion that the condition was not met. See Perales, 402 U.S. at 401. All that is required to meet condition 1 is that symptoms of obstruction exist. The Secretary's witnesses, as discussed above, found that no symptoms were found based on the record, and such finding is amply supported by the record, as detailed by both the ALJ and the Appeals Council. Accordingly, the finding that condition 1 was not met is supported by substantial evidence.

16. The finding as to condition 2 is also supported by substantial evidence. Condition 2 requires that other cases be considered and ruled out. It is clear from the prior discussion of condition 1 that plaintiff did not rule out multiple sclerosis, and the ALJ so found. CAR 550. In adddition, the evidence deemed credible by the ALJ was that many of the patients had some neurological deficiency unconnected to the vertebral arteries. _Id._ Most of the patients had a previous neurological exam. _Id._ As the ALJ found, such indications of positive neurological findings should have led plaintiff into a more thorough investigation. CAR 551. It did not, and the ALJ found that Plaintiff "did not attempt to completely rule out other causes before performing his operation." _Id._ The Appeals Council concurred. CAR 20.

17. This finding is reasonable, given the previous discussion. The ALJ relied on the credibility of the Secretary's witnesses, and that reliance receives strong deference.

It should be recalled that one of the plaintiff's witnesses (Dr. Bonecutter) questioned the existence of multiple sclerosis. Thus, the finding on condition 2 is supported by substantial evidence.

18. Finally, the Secretary is not required to give plaintiff special deference as treating physician. A treating physician's opinion is entitled to great weight only if there is no conflicting evidence. Kuebler v. Secretary of HHS, 579 F.Supp. 1446, 1440 (E.D.N.Y. 1984). As is evident, this case is replete with conflicting evidence. In addition, the ALJ, in disregarding plaintiff's opinions, made findings which set forth specific legitimate reasons for doing so. See Valencia v. Heckler, 751 F.2d 1082, 1088 n.7 (9th Cir. 1985). This is all that is required, and there was no error.

19. Plaintiff argues that he was entitled to a speedy trial in a non-adversary setting. Neither of these issues were raised below, and thus they were not exhausted.

20. Plaintiff argues that the Appeals Council disregarded and rejected the ALJ decision dated April 23, 1984 regarding Gail Morris. This is true. CAR 18. As the Appeals Council noted, the decision in one case will not "negate the [ALJ's] finding that all four criteria for vertebral artery surgery were not met in each of the 24 cases reviewed..." Id. (emphasis in original). This was the finding of the ALJ (CAR 555), and was the issue agreed upon by the parties. CAR 10771 ("the issue is whether or not the subject... surgeries ...were...medically necessary (emphasis added). Thus, it is of no moment that the AlJ found Gail Morris' surgery to be medically necessary, since plaintiff needed to be proven correct in every case to prevail.

21. Plaintiff's final argument concerns two alleged procedural defects: a lost brief and a lost order. The allegedly lost brief, entitled "Appellant's Opening Brief After Hearing De Novo," is dated September 23, 1982. It consists of 217 pages (plaintiff

apparently cannot generate pleadings totalling less than 100 pages), and may be found at CAR 571-798.

22. It is true, that the ALJ's order of February 5, 1982 (*see* plaintiff's Memorandum, Exhibit I) is not included in the record. However, such an omission is not prejudicial, since the ALJ's decision repeatedly refers to it. CAR 534, CAR 534 n.4, CAR 548 (referring to order amending results). The order was not a secret, and merely added the *Federal Register* issue which, as discussed above, plaintiff failed to pursue before the Appeals Council.

23. There are no genuine issues of fact, and defendant is entitled to judgment as a matter of law.

24. To the extent that any of the foregoing Uncontroverted Facts are deemed to be conclusions of law, they are incorporated into these Conclusions of Law.

[1] / Pursuant to Fed.R.Civ.P. 25(d)(1), Otis R. Bowen is substituted as defendant in place of Margaret Heckler.

DATED: Feb. 24, 1987

J. SPENCER LETTS

UNITED STATES DISTRICT JUDGE

PRESENTED BY:

ROBERT C. BONNER

United States Attorney

FREDERICK M. BROSIO, JR.

Assistant United States Attorney

Chief, Civil Division

IAN FAN

Assistant United States Attorney

Attorneys for Defendant

DECISION OF APPEALS COUNCIL

DEPARTMENT OF
HEALTH AND HUMAN SERVICES
SOCIAL SECURITY ADMINISTRATION
OFFICE OF HEARINGS AND APPEALS

In the case of:
S. Allan Hurvitz, M.D., Petitioner
Claim for:
Provider of Services;
Physician Exclusion
Claimant:
Health Care Finance Administration,
Respondent
Docket No. PS-000-00-0215

This case is before the Appeals Council pursuant to a timely request for review filed by S. Allan Hurvitz, M.D., petitioner, in proceedings before the Appeals Council for review of the administrative law judge's decision dated July 13, 1983.

In his decision, the administrative law judge held that the determination to exclude Dr. Hurvitz from all Medicare reimbursement for a period of two years was not an

unreasonable exercise of the Secretary's discretion.

Pursuant to section 405.1563 of Health Care Finance Administration Regulations No. 5 (42 CFR 405.1563), the Appeals Council granted the request for review on January 3, 1984. The Parties involved were notified of such action by the Appeals Council and of their rights with respect thereto.

The petitioner stated that he did not wish an appearance before the Appeals Council to present oral argument. HCFA also did not request an appearance.

LAW AND ISSUES

The administrative law judge's statements in the decision as to the pertinent provisions of the Social Security Act and the Social Security Administration Regulations are incorporated herein by reference and supplemented below.

Section 420.101(a)(2) of Health Care Finance Administration Regulations No. 20 (42 CFR 420.101(a)(2) provides that:

"(a) Payment will not be made under

Medicare for items or services furnished by a practitione, provider, or other supplier of services that HCFA determines has:

(2) Furnished items or services that are substantially in excess of the beneficiary's need or of a quality that does not meet professionally recognized standards of health care;

(b) HCFA's determination under paragraph (a)(2) of this section, that the items or services furnished were excessive or of unacceptable quality, will be made on the basis of reports, including sanction reports, from the following sources:

(1) The PSRO for the area served by the practitioner, provider, or other supplier of services;

(2) State of local licensing or certification authorities;

(3) Peer review committees of fiscal agents or contractors;

(4) State or local professional societies; or

(5) Other sources deemed

appropriate by HCFA."

The general issue to be decided by the Appeals Council is whether the determination by the Secretary to exclude Dr. Hurvitz from all Medicare reimbursement for a period of two years was reasonable and proper and in accordance with applicable Law and Regulation.

The specific issue to be decided is whether the vertebral artery surgeries performed by Dr. Hurvitz were reasonable and medically necessary. This will depend on whether the criteria for vertebral artery surgery (VAS) cited in Medicare Intermediary Manual No. 715 (Medicare Carriers Manual, Tranmittal No. 688) dated September 1978 are met. Specifically, vertebral artery to relieve obstructions to vertebral artery blood flow can be medically reasonable and necessary, but only if each of the following conditions are met:

1. Symptoms of vertebral artery obstruction exists;

2. Other causes have been considered

and ruled out;

3. There is radiographic evidence of a valid vertebral artery obstruction; and

4. Contraindications do not exist, such as coexistent obstructions of multiple cerebral vessels.

EVIDENCE CONSIDERED

The Appeals Council has considered the entire record which was before the administrative law judge, including the testimony at the hearing. In addition, the Council has carefully considered the briefs and arguments submitted by the petitioner and HCFA in this case. The appeals Council's notice of review and the parties' responses thereto have been entered into the record as Exhibit AC-1. Additional evidence has been received and entered into the record as follows:

Exhibit AC-2 - Article entitled "What is Multiple Sclerosis? Clinical Criteria for Diagnosis" (2 pages)

Exhibit AC-3 - Decisions by Administrative Law Judge Edward H. Schiff,

dated January 8, 1980 and April 23, 1984 in the case of Gail Morris.

The attorney for the Department of Health and Human Services has raised an objection to the submission of the decisions relating to Gail Morris as totally immaterial and irrelevant to the issue now before the Appeals Council. The Council notes that in each of the decisions, the administrative law judge concluded that the services provided by Century City Hospital, including vertebral artery surgery, were reasonable and necessary. The Council further notes that in the latest decision of April 23, 1984, the conclusion was based in part on the testimony of Dr. Marmorstein, a medical advisor who appeared at the hearing. The Appeals Council concludes that this material has little or no probative value in the matter now before the Council since the decision in the case of one claimant, namely Gail Morris, would not negate the administrative law judge's finding that all four criteria for vertebral artery surgery were not met in each of the 24 cases

reviewed in connection with the decision to exclude the petitioner.

EVALUATION OF THE EVIDENCE

The administrative law judge's summary in his decision of the procedural history, testimony and the evidentiary facts before him are incorporated by this reference and are not repeated in this decision.

The Appeals Council has carefully considered the extensive brief which the petitioner submitted in connection with his request for review. However, the Council notes that many of the arguments are essentially duplicative of the arguments presented at the hearing and addressed by the administrative law judge in his decision.

Dr. Hurvitz contends that HCFA's presentation of this case was based almost exclusively upon oral testimony from unqualified witnesses, in contrast to Dr. Hurvitz's position which was supported by experts in vertebral artery obstruction and supported by documentary exhibits from pertinent medical literature. In this

regard, Dr. Hurvitz submits that HCFA's witnesses were not experts in the area of vertebral artery insufficiency, having not performed a single vertebral basilar artery surgery, could not agree on the symptoms and were unfamilar with the current medical literature. However, the record shows that HCFA's witnesses had the necessary qualifications to testify in this case. Dr. Augustus Rose is a board certified neurologist and former director of the Reed Neurological Center for investigation of neurological diseases. Dr. David Thompson, a board certified neurologist, is clinical director of the Multiple Sclerosis Center at the University of Colorado. Dr. Roscoe Webb testified that he is a board certified thoracic and cardiovascular surgeon and clinical assistant professor of surgery at UCLA. Dr. Elliot Blinderman is a board certified neurosurgeon, assistant clinical professor of neurosurgery at UCLA, and Chief of Neurosurgery at Cedar Medical Center. Dr. Willam Anderson is a board certified

neurologist in private practice since 1963. Dr. Huritz points out that these physicians have never performed surgry on a vertebral artery; however, the records suggests that here only a few doctors who perform the type of surgery performed in the 24 cases reviewed in this proceeding. The Appeals Council notes that in each case, Dr. Hurvitz performed arteriolysis (the 5th type of surgery cited in Transmittal No. 715). The transmittal indicates that this procedure is only rarely considered to be medically necessary and reasonable for the individual patient and warns contractors to be especially careful in reviewing these claims. Therefore, the surgery done by Dr. Hurvitz is not widely performed. Although HCFA's witnesses have never performed vertebral artery surgery, their medical expertise in the fields of neurology and thoracic and vascular surgery certainly provides a basis for their testimony on symptoms associated with vertebral artery insufficiency and whether other neurologic causes have ben adiologist in private practice since 1959,

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eliminated. Dr. Hurvitz's witnesses share his enthusiasm fo vertebral artery surgery. However, the ALJ found HCFA's witnesses testimony to be more credible than Dr. Hurvitz's witnesses, one of whom doubted the existence of multiple sclerosis. Although Dr. Hurvitz acknowledges the existence of multiple sclerosis, he believed that some individuals carrying the diagnosis of multiple sclerosis have been misdiagnosed.

Dr. Hurvitz also argued that HCFA failed to prove that the patients in questions had multiple sclerosis instead of vertebral artery obstruction (VAO). He points out that Transmittal 715 specifically designates symptoms of VAO and also cites the diseases to be ruled out; however, multiple sclerosis is not mentioned as a cause to be ruled out. In his brief, Dr. Hurvitz reviews each patient individually and concludes that each of the 24 patients had the symptoms alluded to in Transmittal 715, namely "vertigo, visual or speech defects, ataxia, mental confusion or stroke". However, there is no minated. Dr. Horvitz's witnesses state e enthusiasm is particularly strong among owever, the ALJ found Horvitz's witnesses estimony to be more credible than the ertz's witnesses, and it accepts the xistence of multiple sclerosis. Although . Horvitz acknowledges the existence of tiple sclerosis, he believes that some ividuals carrying the diagnosis of tiple sclerosis have been misdiagnosed. Dr. Horvitz also argues that these tables prove that the patients in question had tiple sclerosis instead of depression. ery observation (1980), at 36 [illegible] and the [illegible] (is specifically) has [illegible] ference of [illegible] and high white cell [illegible] g spinal tap, elevated protein levels in nt pertinent as a factor in the [illegible] and nt's brief; Dr. Horvitz's argument [illegible] iant [illegible] and [illegible] that each hese 21 patients [illegible] the [illegible] is Transmitted [illegible] namely Transverse ual or speech defects, ataxia, vertigo otension of [illegible] however, there is no indication that the effects of VOA listed in Transmittal 715 are all inclusive, and in fact the numerous physicians who testified both for HCFA and Dr. Hurvitz as well as the medical literature (Exhibit A-25, A-26) cite a number of other symptoms, e.g. drop attacks. Dr. Hurvitz contends that vertebral artery obstruction is the only disease that causes "drop attacks" (Tr. 2255). Dr. Hurvitz further argues that the "drop attack" is not required for the diagnosis of vertebral artery obstruction, and is never seen in multiple sclerosis. The Appeals Council reserves judgment as to the accuracy of the statement that VAO is the only disease that causes drop attacks since it appears that there are differing opinions on this matter. However, without the drop attack or transient ischemic attack (TIA), a basic characterization which could distinguish vertebral artery obstruction from some othr neurological dysfunction is absent. While a drop attack may not be requied for a diagnosis of VOA, such a phenomenon would

certainly help clarify the diagnosis. The Appeals Council notes with interest that of the four cases where a drop attack is mentioned (Monahan, Knauf, Brayfield, Law) two were age 64, one was 54 and the other was 43 years old at the time of the surgery. If these were true "drop attacks" as opposed to falls due to poor balance, which in the opinion of Dr. Hurvitz would establish the diagnosis of VAO, it would strengthen the argument that symptoms of vertebral artery insufficiency appear for the first time in patients in their sixth decade and older (age 50+) rather than in earlier age groups. Of the 24 cases involved, 15 were under the age of 50 at the time of surgery. 12 were in their 20's or 30's. Transmittal 715 states in addition to VAO, differential diagnosis should include "various degenerative disorders of the brain, orthostatic hypotension, acoustic neuroma, labyrinthitis, diabetes, and hypoglycemic related disorders". While multiple sclerosis is not specifically listed as a differential

ecessarily help clarify the diagnosis. The
ppeals council notes with interest that of
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atients in their sixth decade and older (age
0) rather than in earlier age groups. Of
he 16 cases analyzed, 10 were under the age
f 20 at the time of surgery; 11 were in
heir 20's or 30's. Wynne-Davies (1) states
n addition to the differential diagnosis
ould include "various hypoplastic
nomalies of the hands, ectodermal
ysplasia, [illegible] [illegible], [illegible]
ictures, and hypoplastic pelvis
yndromes". While multiple etiologies are
ertainly involved in a differential

diagnosis, the Appeals Council believes it was incumbent on Dr. Hurvitz to establish the existence of VAO by eliminating other causes for the claimant's symptoms. In this regard, HCFA has presented a strong case that many of patients had multiple sclerosis or some other neurological disorder, yet Dr. Hurvitz failed to refer these patients to a neurologist fo consultation prior to surgery or obtain the neurological record and in some cases complete neuological workups (e.g. Mayo Clinic) which had been performed. Although multiple sclerosis is not mentioned in Transmital 715, the diagnosis was a distinct possibility. Several patients had carried a diagnosis of multiple sclerosis for many years, yet nowhere in Dr. Hurvitz's records did he mention the prior diagnosis of multiple sclerosis or in any way indicate that he considered that diagnosis, even though many of the symptoms of multiple sclerosis and VAO are similar. Although Dr. Hurvitz indicated that he performed sufficient testing including tomograms of the

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brain, skull films, angiograms, EKG, chest films, blood sugar and CBC, tests for syphilis and serum potassium and creatinine, in addition to blood pressure checks, and therefore ruled out the differential diagnoses cited in Transmittal 715, the Appeals Council is of the opinion that HCFA has offered, based on the evidence and testimony, a reasonable alternative to the diagnosis of vertebral artery obstruction which cannot be ignored.

Dr. Hurvitz contends that the ALJ's decision is fatally contradictory in that the ALJ ruled that HCFA failed to prove that radiographic evidence of obstruction did not exist. Dr. Hurvitz argues that, by inference, radiographic evidence of obstruction existed in all 24 patients. Dr. Hurvitz, therefore, concludes that if such obstruction is radiographically proven, then the evidence must establish that the symptoms observed are of vertebral artery obstruction, rather than multiple sclerosis or other neurological dysfunction. The arch aortogram

is the best evidence of a vertebral artery obstruction; however, the interpretation by the radiologist (Dr. Burrows) in each case is vague and equivocal. The interpretation in almost every case had identical vague language. Conflicting interpretations were also offered by the witnesses at the hearing. In weighing the credibility and the competence of the physicians who testified, the administrative law judge concluded that Dr. Hurvitz had reasonable grounds to hold a good faith belief, arguably incorrect though it may be, that the xrays showed an obstruction. The ALJ further indicated that the xrays do not ambiguously show that there is no obstruction. It is apparent from the record and from the conflicting testimony and vague interpretation of the xrays that neither could the ALJ find unambiguously that an obstruction does exist. Although the ALJ has given Dr. Hurvitz the benefit of the doubt based on his misplaced intrpretation of the xrays, it is also apparent that in view of the unesolved conflicts, the existence of

an obstruction has been neither confirmed or disproven. Although the ALJ has found that condition 3 was satisfied, it is obvious that he basis of this finding was Dr. Hurvitz's good faith acceptance of the xray interpretation rather than based on actual proof that an obstruction was conclusively present. In this regard, the Appeals Council recognizes that the medical criteria and specific indications for surgical procedures in vertebral artery lesions are still undergoing evaluation and this is a field without definitive answers; however, the Appeals Council is of the opinion that criteria #3, i.e. radiographic evience of a valid vertebral artry obsruction, is of major importance in a decision to undertake a surgical procedure. Consideration of a patient for surgery involving a vascular structure necessitates demonstration that the symptoms presented are attributable to a significant correctable obstruction.

Dr. Hurvitz reiterated the same contentions regarding his allegations of

denial of due process that were addressed in the hearing decision. He argues that sanctions were imposed based on recommendations of ineligible reviewers and without making the required specific findings of fact and fault and that he was denied an effective opportunity to present a defense. He also alleges that the PSRO law is unconstitutional and that due process requires a full evidentiary hearing prior to imposition of sanctions. These charges were discussed in the ALJ's decision (pp.3-6). The ALJ found no merit or factual foundation to those contentions and summarily disposed of them. Specifically, Dr. Hurvitz contends that sanctions were based on opinions by inelegible reviewers, citing that the PSRO reviewers were not his peers as required by 42 CFR 466.2 because they were not in the same professional field. Dr. Hurvitz holds this view because the PSRO physicians and HCFA's witnesses do not practice in the specialty diagnosis and surgical treatment of vertebral basilar artery insufficiency.

However, the Appeals Council does not concur. The Council is of the opinion that it was not the intent of this section of the Regulations to so narrowly limit the number of reviewers by requiring specialists in the precise medical specialt, thus eliminating reviewers with related backgrounds and medical specialities. Dr. Hurvitz also charges that the PSRO failed to notify him of the specific finding of fact and fault before imposing sanctions. Section 474.10(d) of 24 CFR provies that when HCFA decides to impose a sanction, it will notify the practitioner of the determination. The notice will specify the basis of the determination, the sanction to be imposed, the effective date and duration, the appeals right and the earliest date that HCFA will accept a request for reinstatement. A notice covering each of these points was sent to Dr. Hurvitz on July 29, 1980 (Exhibit R-7). The notice also discusses in detail the steps leading to the decision to impose sanctions and numerous opportunities for Dr. Hurvitz to met with the

PSRO and HCFA to defend his position.

Dr. Hurvitz argues that the PSRO law was unconstitutional and that due process required that he receive a full evidentiary hearing prior to the impositions of sanctions. He maintains that because of his loss of his livelihood and the substantial curtailing of his practice and resulting psychological suffering and loss of reputation, a pre-termination hearing was required. The ALJ thoroughly cites the reasons that no right to a fully evidentiary pre-termination hearing exists, including specific court precedents. In this regard, the ALJ noted the potential harm to the public caused by unnecessary, unreasonable or substandard medical care outweighs the potential harm to the appellant's practice of medicine. The Appeals Council concurs and believes that practitioners are entitled to a hearing only after the determination to impose sanctions has been made and that the Social Security Act and Regulations do not provide for pre-termination hearings.

Finally, Dr. Hurvitz contends that, even if some type of sanction should have been imposed, less sanctions were available to HCFA and the 2 year sanction was unreasonable and unjust. However, Section 42 CFR 420.114(a)(2) of HCFA Regulations (formerly Section 420.103(a)(2)) provides the basis for the length of an exclusion. HCFA has considered this criteria and has reduced the exclusion from 5 years, as previously recommended by Statewide Council, to 2 years. Testimony at the hearing by Paul Gottlober, HCFA Program Analyst, Office of Program Integrity, indicates that 9 persons have been excluded under Section 1862(d) or 1160 of the Act since 1978 in the San Francisco Region. Some exclusions were for an indefinite period and the average length of the remaining 7 was six years. (Tr. 1315) By comparison, Dr. Hurvitz's exclusion was moderate according to Mr. Gottlober. In setting the duration of the exclusion, HCFA considered that patients had incurred out of pocket costs and subjected themselves to some risk in having

the surgery. In addition, no mitigating circumstances were noted and Dr. Hurvitz was unwilling to change. The Appeals Council notes that Dr. Hurvitz testified that he stopped performing the surgery on Medicare patients after his waiver of liability was withdrawn. Based on all the evidence of record, the Appeals Council concludes that, in each of the 24 cases, the surgery did not meet all four established criteria for payment and was not medically reasonable and necessary. Accordingly, the Appeals Council is of the opinion that a two year exclusion was justified.

FINDINGS OF THE APPEALS COUNCIL

After careful consideration of the entire record, the Appeals Council adopts the findings and conclusions of the ALJ, specifically, that not all of the four criteria for vertebral artery surgery contained in Transmittal No. 715 were met in the case of each of the 24 patients reviewed.

DECISION

It is the decision of the Appeals Council that the determination by the Secretary to exclude the paetitioner from all Medicare reimbursement for a period of two years was reasonable and proper and in accordance with applicable Law and Regulations. The decision of the ALJ is affirmed.

APPEALS COUNCIL
Harriet A. Simon, Member
Burton Berkley, Member
Maria Segarra, M.D., Member

Date: January 14, 1985

DECISION OF ALJ

DEPARTMENT OF
HEALTH AND HUMAN SERVICES
SOCIAL SECURITY ADMINISTRATION
OFFICE OF HEARINGS AND APPEALS

In the matter of:

S. ALLAN HURVITZ, M. D.,

Appellant.

Docket No. PS-000-000-215

DECISION

I. Introduction

In an initial determination dated July 29, 1980, an agency of the Federal Government kanown as the Health Care Financing Administration (hereinafter "HCFA") proposed to exclude the Appellant, S. Allan Hurvitz, M.D., from any reimbursement under the Medicare program for all items and services rendered by him to Medicare patients for a period of two years. 1 / Dr. Hurvitz incurred the wrath of the Government for allegedly performing medically unnecessary vertebral artery surgery on Medicare patients in violation of section 1862(d)(1)(C) 2 / of the Social Security Act (hereinafter "the Act"),

42 U.S.C. 1395y(d)(1)(C), and in contravention of regulations at 42 CFR 420.101(a)(2), 101(b), 102(a)(1) and (2), and 102(b)(1) (Ex. R-49). However, considering HCFA's determination to be incorrect and pursuant to 42 CFR 405.1501(a)(6) and 1580, Dr. Hurvitz sought and received a hearing on the matter which was held before the undersigned. 3 /

The prehearing agreement between the parties dated January 23, 1981, later amended by the undersigned on February 5, 1982, sets out the issues which must be resolved in this dispute, namely: whether the subject surgeries which Dr. Hurvitz performed were medically reasonable and medically necessary based on the fact that in each case symptoms of vertebral artery obstruction existed, other causes were considered and ruled out, radiographic evidence of a valid vertebral artery obstruction existed, and contraindications such as coexistent obstructions of multiple cerebral vessels did not exist; and whether the undersigned is

bound by the noted four criteria in determining the reasonableness and the necessity of the vertebral artery surgery or whether independent judgment can be exercised in determining the medical necessity of the operations. 4 /

For the reasons that follow it is the decision of the undersigned that not all four of the four criteria outlined above were shown to have been met in the records of the relevant surgeries under examination in the instant cases. 5 / Therefore, because the surgeries by Dr. Hurvitz did not meet all of the requirements of each of the four criteria, they were not medically necessary and were not medically reasonable. Thus it was not an unreasonable exercise of the Secretary's discretion to exclude from Medicare reimbursement for two years all items and services rendered by Dr. Hurvitz because of his performance of medically unnecessary and unreasonable vertebral artery surgery in violation of the Social Security Act. 6 /

II. Procedural Regularity

Since a substantial portion of the Appellant's post-hearing brief, more than half, is devoted to an attack on the procedures used by the various agents of the Secretary in arriving at the decision to terminate Dr. Hurvitz from Medicare reimbursement coverage, it will be necessary to briefly address that issue before proceeding to an examination of the substantive issues involving the four criteria noted above. 7 / In this regard, the record reflects that at least since 1976 (Ex. A-153), Dr. Hurvitz was involved in a continuous struggle with many levels of the state, federal and medical insurances bureaucracies which set standards for Medicare operations in an attempt by him to establish the medical necessity of, and therefore coverage of and payment for, surgical procedures designated as vertebral artery surgery, an operation which at least part of the national medical community regard as "rare," some as "investigational," and

others as "well established" (Ex. R-103).

Dr. Hurvitz estimated at the hearing that he has performed 400 vertebral artery operations in his professional lifetime (TR: 160, red). Dr. Hurvitz's efforts in this regard, and heavy involvement in attempts to justify vertebral artery surgery, are well documented (Exs. R-103, 104). Suffice to say that by September 1978, the four criteria necessary for Medicare reimbursement which Dr. Hurvitz is alleged to have violated in the performance of the 24 vertebral artery surgeries under examination in this case were established and publicized in HCFA's Medicare intermediary manual (Ex. R-1, Transmittal No. 715). This publication came into being well before the first of the violative surgeries here under scrutiny took place in November 1978 (Ex. R-1). Transmittal No. 715 notes that vertebral artery surgery would be considered reasonable and necessary only if symptoms exist, other causes are ruled out, radiographic evidence substantiates the obstruction, and contraindications to the

procedure do not exist (Ex. R-1). Despite this heavy burden for justifying any vertebral surgery, however, which, as noted, Dr. Hurvitz himself helped establish, he operated on twenty-four patients for alleged vertebral artery obstruction from November 1978 until February 1979 (Ex. R-8 to R-31). Those twenty-four operations are the subject of this litigation.

As a result of Dr. Hurvitz's performance of the operations, the Executive Committee of Area 22 of the Professional Standards Review Organization (hereinafter"PSRO"), 8 /after several preliminary investigations and reviews to determine the reasonableness and necessity of the surgeries involved, notified Dr. Hurvitz on June 26, 1979 that he had violated his obligations under the Act by not providing health care services which were meically necessary since he failed to show that the records of the 24 surgeries met all of the four criteria in Transmittal No. 715 (Ex. R-40. As a result, and additionally because Dr. Hurvitz declined and refused to

meet with the PSRO to discuss the violations, the Area 22 PSRO issued a report and recommendation of sanctions to the California Statewide PSRO Council, San Francisco, California (Ex. R-4). The Council affirmed the report and sanctions recommendations after what it noted was a thorough and intensive review (Ex. R-43). On September 27, 1979, HCFA's regional office in San Francisco, California, forwarded to its headquarters in Baltimore, Maryland, the Statewide PSRO Council's proposal to exclude Dr. Hurvitz from coverage under Title XVIII, section 1862(d)(1)(C), of the Social Security Act, with a recommendation "that the exclusion be for five years" (Ex. R-44. As noted above, HCFA's headquarters office in Baltimore, Maryland, effectuated the exclusion for two years, not five, in an initial decision dated July 29, 1980 (Exs. R-48 and R-49).

The undersigned agrees with the Secretary that these procedures adequately safeguarded Dr. Hurvitz's right to due

process of law under the United States Constitution. Moreover, the procedural steps themselves which were required by the Act and its implementing regulations in order to exclude Dr. Hurvitz from the reimbursement coverage were followed in detail as briefly summarized above. Dr. Hurvitz had notice of the criteria since he helped draw up the standards which he allegedly did not follow, he was repeatedly given the chance to submit evidence in his favor, he was given many opportunities to defend his position, and yet he is now heard to complain after a prolonged administrative review involving the deliberation of many individuals and after the submisson of much documentation that his due process rights have been violated (Appellant's Brief, pp. 22 through 122). The undersigned finds no merit to these contentions and summarily disposes of them. They lack a factual foundation.

It is well established that a physician subject to exclusion from Medicare reimbursement has no right to a full

evidentiary pre-termination hearing. There is no right to a hearing because the potential harm to the public caused by unnecessary, unreasonable, or substandard medical care outweighs the potential harm to the Appellant's practice of medicine; because Appellant must first exhaust his administrative remedies; and because any harm to the Appellant's medical practice resulting from the running of the suspension can be recouped if the physician ultimately prevails. Kwoun v. Schweiker, 528 F.Supp. 1004 (E.D.Missouri 1981). Furthermore, as noted above, the statutory provisions under which Dr. Hurvitz was excluded from Medicare reimbursement have withstood constitutional attack and have passed due process muster. Association of American Physicians and Surgeons v. Weinberger, 395 F. Supp. 125 (R.D.Ill. 1975), aff'd 423 U.S. 975, 96 S.Ct. 388, 46 L.Ed.2d 299 (1975). Therefore, because Dr. Hurvitzhad notice and, even helped draft the standards for vertebral artery surgery which he allegedly violated;

because all of the procedural steps required by the Secretary's valid regulations were substantially complied with, including notice and an opportunity to defend; because Dr. Hurvitz had no right to a full evidentiary pre-suspension hearing; and because the statutory scheme under which he was excluded is constitutional on due process grounds, the Appellant's due process arguments must fail.

9 / In effectuating the suspension, the Secretary complied with the law and her own regulations, notice was given to the Appellant, a rational basis was laid for the suspension, and all required procedural steps were followed.

III. Symptoms of Obstruction

Symptoms of blockage of blood through the vertebral arteries can include drop attacks, dizziness, vertigo, visual defects, speech defects, muscle incoordination, mental confusion, headaches, audible bruits and thrills, vomiting, weakness, deafness and a diminished pain sensation (Exs. A-25, A-26. and A-36). The evidence in this case

concerning the issue of the alleged existence or lack of symptoms of vertebral artery obstruction introduced at the hearing is vast, but largely cumulative. The only question at this point is whether the 24 patients under examination here had the necessary symptoms of an obstruction before surgery in order to satisfy the first of the Secretary's four criteria.

Dr. David Stuart Thompson, a board certified neurologist and assistant professor of neurology at the University of Colorado Medical Center, Denver, Colorado, testified for the Government that an insufficiency of blood supply to the posterior portion of the brain causes transient symptoms of vertigo, dizziness, blurring of vision, ataxia, and black outs. He emphasized that the symptoms are transient, occurring over only a period of minutes to hours (TR:1542). He pointed out, however, that none of the records of seven of the involved patients here under discussion contain symptoms of a vertebral artery insufficiency (TR: 1564-1565). He

noted, rather, that all seven of the patients had symptoms of multiple sclerosis (TR: 1564-1565). 10 / He pointed out that he has examined roughly 600 multiple sclerosis patients (TR:1539). He stated that it is extremely rare to find a case of vertebral artery insufficiency in persons between the ages of twenty and forty (TR: 1577). He found it highly unusual, moreover, that Dr. Huritz's records of twelve of the patients under scrutiny contained almost identical descriptions of similar symptoms (TR:1541).

Dr. William Anderson, a board certified neurologist and clinical staff professor at the University of California Medical School, San Francisco, California, testified for the Government that in at least 12 of the cases under review no symptoms of vertebral artery obstruction appear in Dr. Hurvitz's records (TR: 445-597). He repeated later in his testimony that there were no symptoms of vertebral artery obstruction in the records of patient Simone (TR:611). Further, Dr. Augustus A. Rose, a board certified

neurologist and retired full professor of neurology at UCLA Medical School, Los Angeles, California, testified that the records of 14 of Dr. Hurvitz's patients (TR:1113) describe virtually the same symptoms in each but that the records themselves fail to show the existence of symptoms of vertebral artery obstruction (TR: 1142). Additionally, Doctor Roscoe Webb, a board certified thoracic surgeon, a practicing cardiovascular surgeon, and an assistant clinical professor of surgery at UCLA, testified that symptoms of vertebral artery insufficiency are "transient" (TR:845). He pointed out that although he considers himself an expert in vascular surgey, he would rely heavily on the assistance of a neurologist to help diagnose vertebral artery syndromes (TR: 956).

Dr. Elliot E. Blinderman, a board certified neurosurgeon, an assistant clinical professsor of neurosurgery at UCLA, and a member of the state bar of California, testified that symptoms of vertebral artery

blood flow blockage should be classified in two ways. First, vertebral artery "insufficiency" exhibits a well recognized set of transient symptoms including a brief loss of nerve function, loss of tone in both legs, drop attacks, double vision, nausea, and vomiting (TR: 944). The symptoms are reversible and after the "attack" the patient "always gets better" (TR:994). He reiterated that this small vessel disease inside the head is "very, very rare"(TR: 994). In light of this definition, he noted that Gail Morris' records (Ex. R-26) show symptoms more consistent with multiple sclerosis, which presents in its classic form a neurologic deficit in a young person (TR: 996).

Dr. Blinderman continued that the records of Jymme Knauf (Ex. R-8) show symptoms of multiple sclerosis, not vertebral artery obstruction, because of the presence of multiple sclerosis in the nervous system disseminated in time and space (TR: 1006); that Leroy Russell (Ex. R-10) had symptoms of multiple sclerosis not vertebral artery

obstruction because the patient could not walk (TR: 1009-1010); that the records of Judith Baker (Ex. R-9) show symptoms of disseminated sclerosis or some other disease but not vertebral artery obstruction (TR: 1011-1012); that the records of Mark Simone (Ex. R-20) do not show the the existence of symptoms of vertebral artery obstruction but rather some form of multiple sclerosis resticted to the spinal cord because the patient was essentially a paraplegic in the legs (TR: 1013-1015); that the records of Harry Green (Ex. R-18) show no symptoms of vertebral artery obstruction but rather symptoms of a degenerative disease of the nervous system because of the patient's cognitive problems (TR: 1017-1018); that the records of John Subbert (Ex. R-22) show symptoms of spinocerebellar degeneration not vertebral artery obstruction because of leg ataxia and spinal column deficits (TR: 1020); that the records of Ruth Brayfield (Ex. R-13) show symptoms of a central nervous system disease not vertebral artery obstruction

because of her longstanding balance and gait problems (TR: 1023-1024); and that the records of Leone Monahan (Ex. R-19) exhibit symptoms of multiple sclerosis or spinocerebellar dystrophy because of her disturbed brain function and do not show symptoms of vertebral artery obstruction (TR: 1025-1026).

Dr. Bernard Townsley, a physician and senior medical advisor to Blue Cross of Southern California, Inc., Woodland Hills, California, testified for the Government that the records in this case of Ruth Brayfield, Darlene Noffsinger, Vivian Law, Richard Wilson, Donna Lally, Keith Anderson, Sylvia Hall, Margaret Klemme, Mark Simone, Leone Monahan, and Kanya Canterbury do not contain symptoms of vertebral artery obstruction because all of the noted patients' files documents longstanding chronic illnesses whereas vertebral artery obstruction exhibits symptoms of a transitory nature, like temporary disturbances of equilibrium or possible visual disturbances (TR: 1211-1213).

For example, he noted that in the case of Donna Lally (Ex. R-54) the records show longstanding bowel problems, bladder problems, and spasticity of the muscles, all of which are not found in patients with the transient symptoms found in vertebral artery obstruction (TR: 1218). He stated that the history of the above patients' diseases as documented in their records do not fit the symptoms od vertebral artery obstruction (TR: 1244). He stated that when they were presented for payment he "totally rejected" them (TR:1252).

Dr. Jonas V. Mileris, a surgeon and board certified neurologist from Bourbannais, Illinois, testified for the Government that he diagnosed multiple sclerosis for patient Judith Baker (TR: 5020, 5024) and has not at any time diagnosed vertebral artery insufficiency for her (TR: 5022). He stated that the patient had symptoms of divergent neurological dysfunction, including ataxia, dystaxia, nystagmus, slurred speech, atrophy of the optic nerve, and absent abdominal

reflexes or Babinski signs (TR: 5024; Ex. R-106).

On the other hand, Dr. Glen Bonecutter, a neurologist from Los Alamitos, California, who assisted Dr. Hurvitz with many patients (TR: 1812), testified that "absolutely" each and every one of the 24 patients here under examination had symptoms of vertebral artery obstruction (TR: 1818-1819). He stated that the patients' histories were "compatible with disease in the vertebral basilar arterial system" (TR: 1822), and he asserted that the symptoms can be chronic, lasting for years, as well as transient (TR: 1822). He listed the symptoms as motor weakness, slurred speech, difficulty swallowing, decreased mental capacity, urinary bladder disorder, and dysfunction of the bowel (TR: 1824-1827). Contrary to the assertion of authors Bradshaw and McQuaid (Ex. A-9) that most sufferers of vertebral artery disease are middle aged or elderly, Dr. Bonecutter stated that symptoms of vertebral artery obstruction are not

unusual in patients under 31 years old (TR: 1861-1862). On the other hand, Dr. Bonecutter was not so sure that there is such a disease as multiple sclerosis; he noted that many patients diagnosed with symptoms of multiple sclerosis actually have vertebral artery obstruction (TR: 1872-1880). He noted that at least one of the 24 patients in this case had signs and symptoms "compatible with the usual misguided textbook description" of multiple sclerosis (TR: 1894). He thought it "possible", however, to have both multiple sclerosis and vertebral basilar artery insufficiency (TR: 1899).

Dr. Ward W. Woods, a board certified neurologist and neurosurgeon from San Diego, California, testified for the Appellant that the symptoms of vertebral artery obstruction are dizziness, postural vertigo, blurred vision, nausea, vomiting, loss of memory, loss of concentration, and pressure on the nerves that serve the four extremities (TR: 2066). The symptoms, he said, be transient or chronic (TR: 2071). He certified that all of the patients' records involved in this case fulfill the four criteria required for vertebral artery surgery by Transmittal No. 715 (Ex. 1-90) and that all of the records show the existence of symptoms of vertebral artery obstruction. He did not believe that the most likely diagnosis for the 24 patients here under scrutiny is multiple sclerosis (TR: 2074). In fact, he stated that he agreed with the approach in an unspecified publication the Dr. Hurvitz wherein the Appellant is described treating nine previously diagnosed multiple sclerosis patients with vertebral basilar artery insufficiency surgery (TR: 2090). He disagreed with Myer and Bilroy's assertion (Ex. A-36) that symptoms of vertebral basilar artery insufficiency usually appear for the first time in patients in the sixth decade of older (TR: 2096-2097). He stated, however, that disease of the vertebral

arteries can mimic multiple sclerosis (TR: 2098; Ex. A-25, p. 148), and that multiple sclerosis characteristically begins in younger patients and leaves lasting neurologic deficits (TR: 2099). He listed the following symptoms for multiple sclerosis: spasticity, weakness of the extremities, incontinence, paresthesia, dysarthria, tremor, ataxia, nystagmus, impaired vision, facial weakness, and impaired gait (TR: 2104-5). He concluded that he does not think Dr. Hurvitz is an expert in recognizing the signs and symptoms of multiple sclerosis (TR: 2125) but that the diagnosis of vertebral basilar artery insufficiency is often overlooked (TR: 2211).

Dr. Sigmond Wesolowsky, a surgeon from Lynnfield, Massachusetts, testified for Dr. Hurvitz that the records of all 24 patients in this case show the existence of symptoms of vertebral artery obstruction, including loss of equilibrium, loss of balance, dizziness, fatigue, dis-coordination, bladder dysfunction, double vision, numbness in the feet, slurred speech, incontinence, headaches, depression, nystagmus, difficulty swallowing, spasticity, drop attacks, ringing in the ears, rigidity, slow mentation, memory loss, grip weakness, head tremor, weakness in the back muscles, foot drop, vertigo,

and somnilescence (TR: 2224, 2247-2248, 2255, 2260, 2262-2263, 2265-2266, 2268-2269, 2274-2275, 2276-2277, 2279-2281, 2282-2283, 2284-2285, 2287-2288, 2289-2290, 2292-2293, 2294-2295, 2300-2301, 2302-2304, 2305-2306, 2308-2309, 2313-2314, 2315-2316, and 2318-2319). He pointed out that the severity of the symptoms can be magnified by turning the head (TR:2261). On cross examination, he noted that if a person had a congenital vertebral artery aberration the symptoms could show up in early childhood (TR: 2388). He did not find it unusual that many of the 24 patients under scrutiny here were in their twenties or thirties when operated on by Dr. Hurvitz (TR: 2389). He was of the opinion that all 24 patients had symptoms of a "neuro-vascular disease" (TR: 2393). He agreed that vertebral artery obstruction is an illusive and difficult diagnosis (TR: 2398).

Finally, Dr. Hurvitz himself, a diplomate of the American board of surgery and thoracic surgery from Los Angeles, California, testified at the hearing that the signs and symptoms of vertebral basilar artery insufficiency, which can be transient or chronic, are as follows: a disorder of equilibrium, a disorder of balance, a disorder of gait, ataxia,

lack of coordination in the extremities, dizziness, decreased sensation in the face, a swallowing disorder, blurred vision, slurred or slowed speech, drop attacks, sensory deficits, a urinary disorder, postural vertigo, constipation, decreased mental capacities, headache, and memory lapse (TR: 2491, 2515). He testified that the records of Keith Anderson (Ex. A-58), show, a 46 year old individual with symptoms since 1973 of slurred speech, unsteady gait, loss of balance, dystaxia, hand tremor, weakness of grip, loss of sensation in the right leg, fatigue, a urinary disorder, a vision disorder, a lack of coordination, headaches, decreased hearing, constipation, and irritability (TR: 2628, 2633); that the records of Judith Baker (Ex. A-59) show a 40 year old female with symptoms since 1970 of weakness in all extremities, headaches, depression, slurred speech, blurred vision, a urinary bladder disorder, trouble swallowing, constipation, dizziness on postural change of the head, neck weakness, nystagmus, an inability to stand, paralysis of the right upper limb, tremor in the left upper limb, neck muscle weakness, and an absent right hand grip (TR: 2647-2651); that the records of Ann Boshart (Ex. A-60) show a thirty year old female with symptoms since 1972 of difficulty balancing, a disorder or equilibrium, numbness in

the lower limbs, the need for crutches, spasticity in the lower limbs, a loss of coordination, dystaxia, blurred vision, headaches, difficulty swallowing, urinary bladder disorder, nystagmus, an unsteady gait, right foot drag, and decreased vibration in both great toes (TR: 2665-2673); That the records of Ruth Brayfield (Ex. A-61) show a 64 year old individual with symptoms since 1964 of drop attacks, a loss of balance, rigidity and spasticity in the lower limbs, severe tinnitus, constipation, neck pain, a urinary bladder Dysfunction, depression, numbness in the upper limbs, numbness around the mouth, headaches, tinnitus, decreased hearing, constipation, and nystagmus (TR: 2680-2684); that the records of Kenya Canterbury (Ex. A-62) show a 31 year old female with symptoms since 1974 of a loss of equilibrium, difficulty walking, severe falling, right lower limb drag, slurred speech, blurred vision, dystaxia and ataxia in the upper limbs, decreased mental process, trouble swallowing, urinary bladder disorder, "problems with... eyesight," and weakness and tremors in the hands (TR: 2690-2697); that the records of Harry Green (Ex. A-63) show a 77 year old individual with symptoms since 1972 of incoordination, loss of balance, frequent falls, loss of memory, slurred speech, urinary

frequency, sleep most of the day, constipation, difficulty walking, ataxia in the lower extremities, grip weakness, and dystaxia in both legs (TR: 2703-2708); that the records of Sylvia Hall (Ex. A-64) show a thirty year old female with symptoms since 1972 of blurred vision, a problem with equilibrium, weakness in the lower limbs, constipation, lack of upper and lower limb coordination, head tremor, urinary bladder disorder, slowed speech, trouble swallowing, decreased mental capacities, left hand ataxia, nystagmus, weakness in grip strength, severe ataxia, and back muscle weakness (TR: 2713-2717); that the records of Sheila Harvey (Ex. A-65) show a 25 year old female with symptoms from 1972 of decreased visual acuity, blurred vision, a lack of equilibrium, weakness in the lower limbs, a speech disorder, numbness in the hands, dystaxia and dysmetria in the hands, tremors in the arms and hands, trouble walking, a urinary bladder disorder, and constipation (TR: 2744-2750); that the records of patient Helen Ives (Ex. A-66) show a 37 year old woman with symptoms since 1957 of double vision, head numbness, loss of balance, weakness in the left leg, urinary frequency, incontinence, pain and numbness on the left side of the body, frequent falls, trouble focusing her eyes, decreased memory, constipation,

fatigue, and dizziness on flexing the neck forward (TR: 2757-2760); that the records of Donna Jones (Ex. A-67) show a 30 year old individual with unmistakable sings and symptoms of vertebral artery insufficiency since 1966 including stumbling, lack of coordination, loss of balance, weakness in the left leg, decreased vision, lightheadedness, headaches, urgent and frequent urination, severe fatigue, loss of grip strength, and constipation (TR: 2764-2766); that the records of Margaret Klemme (Ex. A-68) show a 52 year old patient with symptoms from 1953 of pain in the neck, a loss of balance, weakness in both legs, an inability to write, headaches, and back weakness (TR: 2772-2773); that the records of Jymme Knauf (Ex. A-69) indicate a 43 year old lady with symptoms from 1952 of loss of arm and grip strength, dizziness and vertigo when standing up quickly or on postural changes, leg aches, drop attacks, fatigue, low back aches, a loss of balance, leg weakness, right arm weakness, falling spells in a dark room, constipation , a urinary disorder, a loss of memory, depression, hazy vision, and tenderness in both ears (TR: 2778-2782); that the records of Donna Lally (Ex. A-70) show a 35 year old female with symptoms from 1971 of severe headaches, fatigue, a loss of balance, weakness in the right leg, right foot drag, a loss of

grip strength in the hands, frequent falls, profound leg weakness, urinary bladder disorder, occasional blurred vision, cold hands and feet, decreased mental capacity, occasional trouble swallowing, and a decrease in recent memory (TR: 2787-2790); that the records of Vivian Law (Ex. A-71) reveal a 64 year old individual with symptoms since 1964 of a loss of balance, intermittent postural dizziness, fatigue, a urinary bladder Dysfunction, constipation, drop attacks, and a slight decrease in memory (TR: 2794-2796); that the records of Leone Monanan (Ex. A-72) show a 54 year old woman with symptoms since 1963 of falls, drop attacks, a loss of balance, weakness in the legs, headaches, right eye flickering, right foot drag, a swallowing disorder, urinary bladder dysfunction, constipation since childhood, a decrease in mental capacity, a loss of grip strength, labored walking, low back pain, muscle spasticity in the thighs, intermittent blurred vision, and a swallowing disorder (TR: 2810-2812); that the records of Gail Morris (Ex. A-73) show a 36 year old female with symptoms since 1966 of heavy menstrual flow, temporary right-sided paralysis, right-sided weakness and dystaxia, a lack of balance, trouble swallowing, difficulty thinking and concentrating, slurred speech, a lack of coordination, partial loss of vision,

constipation, a urinary bladder disorder, fatigue, dizziness on postural changes, right foot turn, and physical awkwardness (TR: 2818-2820); that the records of Darlene Noffsinger (Ex. A-74) contain unmistakable signs and symptoms of vertebral artery insufficiency because this 45 year old woman, beginning in 1964, had facial numbness, a loss of balance, weakness in the left leg and foot, a urinary disorder, fatigue, constipation, a swallowing disorder, headaches, tinnitus, a decease in memory, intermittent falls, and left foot drop (TR: 2833-2835); that the records of Louis Rozzi (Ex. A-75) show a 56 year old man with symptoms since 1960 of numbness of the right leg and arm, difficulty speaking , a loss of balance, weakness in the legs, decrease memory, a lack of arm coordination, slow reactions, a lack of grip strength, decreased hearing, and a urinary disorder (TR: 2845-2847); that the records of Leroy Russell (Ex. A-76) show a 38 year old make with symptoms since 1966 of a loss of balance, slurred speech, limb weakness, a urinary disorder, constipation, back pain, a decreased mental capacity, and dizziness (TR: 2852-2854); that the records of Philip Sidentop (Ex. A-77) reveal a 68 year old male with signs since 1977 of a need for sleep, a loss of balance, a weak voice, trouble writing, dizziness, on positional changes of the

head, frequent falls, blurred vision, a loss of depth perception, trouble speaking, and constipation (TR: 2861-2867); that the records of Mark Simone (Ex. A-78) show a 25 year old person with symptoms since 1974 of hand tremors, loss of balance, leg weakness, inability to walk, confinement to a wheelchair, trouble swallowing, arm ataxia, slurred speech, a urinary disorder, head tremor, impaired vision, headaches, constipation since childhood, and poor coordination (TR: 2871-2872); that the records of John Subbert (Ex. A-79) indicate a 29 year old make with symptoms since 1973 of a loss of balance, weakness in the legs, dystaxia in the left hand, falling spells, full time confinement to a wheelchair from 1978, slurred speech, a swallowing disorder, troubling using his hands, a urinary disorder, decreased visual acuity, slow thought processes, tinnitus, and constipation (TR: 2876-2879); that the records of Alice Van Cleave (Ex. A-80) show a 54 year old female with symptoms since 1966 of a loss of balance, leg weakness, confinement to a wheelchair, double vision, a urinary, disorder, a swallowing disorder, loss of grip strength on the left, decreased memory, slowed mental processes, and fatigue (TR: 2884-2886); and finally that the records of Richard Wilson (Ex. A-81) reveal a 31 year old man with symptoms

since 1970 of loss of balance, leg weakness, arm dystaxia, a urinary disorder, spasms of the facial muscles, head throbs, fatigue, cold hands and feet, leg spasticity, dizziness and nausea on sudden head motion, headaches, poor vision, tinnitus, a swallowing disorder, constipation since childhood, and difficulty thinking (TR: 2889-2892). It was his opinion that the records in each of the 24 cases examined above demonstrate the existence of symptoms of vertebral artery insufficiency (TR: 59, red).[11]

On cross examination, Dr. Hurvitz did not agree that symptoms of vertebral artery obstruction appear for the first time in patients in the sixth decade of older (TR: 88, red; Ex. A-36), although he agreed that multiple sclerosis symptoms characteristically begin in younger patients (TR: 90, red; Ex. A-25). He agreed that 12 of the patients here under discussion were severely disabled (TR: 102-105, red), but disagreed with authors Bradshaw and McQuaid that severe disablement is uncommon in patients with vertebral artery insufficiency (Ex. A-9, page 294; TR: 105, red). Dr. Hurvitz noted that most of the 24 patients had symptoms progression for more than two years but could point to no authority or source for the proposition that obstruction of the vertebral artery produces

symptoms for more than two years except for an article written by himself (TR: 115-116, 189-201, red; Ex. A-91). He affirmed that he has operated on the vertebral arteries of patients who have had a prior diagnoses of multiple sclerosis (TR: 122-123, 125, red). He noted that drop attacks and transient ischemic attacks distinguish vertebral artery obstruction from multiple sclerosis (TR: 185-186, red). A transient ischemic attack was described as dizziness on arising, dizziness on turning the head, postural dizziness, fatigue, nausea, temporary bladder disorder, difficulty swallowing, and aspiration on drinking, all of which last for up to 1/2 day (TR: 186-187); whereas with multiple sclerosis the same symptoms can appear but last for months before remission and then further exacerbation (TR: 180, 187).

With respect to patient Sidentop, Dr. Hurvitz testified on cross examination that nothing in this patient's records show that he had dizziness in any position, despite the fact that Dr. Hurvitz testified on direct examination that Mr. Sidentop's records show that he had dizziness on postural changes of the head (TR: 4264); and retracted his direct examination statement that patient Wilson had symptoms of dizziness, nausea, and loss of balance on sudden head motion by

admitting on cross-examination that the records of Mr. Wilson's neurological examination on admission to the hospital for vertebral artery surgery are devoid of symptoms of dizziness, nausea, or loss of balance on suddenly turning his head (TR: 4468-4470; Ex. A-81).

Based on the foregoing summary of the evidence, it appears to the undersigned that not all of the records of the 24 patients under examination show the existence of symptoms of vertebral artery obstruction.[12] There is a lack of proof on the existence of symptoms of an obstruction.[13] The Government has shown by a preponderance of the evidence that the records of the 24 patients under review do not, each and every one, show the existence of symptoms of vertebral artery obstruction. There is one very important reason for this conclusion, which follows.

Dr. Hurvitz himself testified that the two symptoms which distinguish vertebral artery obstruction from any other cause, especially multiple sclerosis, are drop attacks and transient ischemic attacks (TR: 185-186, red). Dr. Hurvitz's witness, Dr. Wesolowsky, testified that he considers the "drop attack" to be "pathognomonic" for vertebral artery disease, in other words, a finding of drop attack "makes" the diagnosis of

vertebral artery obstruction (TR: 2255). He knew of no other condition besides vertebral artery obstruction that produces the drop attack symptom (TR: 2255). A review of the evidence and the available literature on the subject substantiates Dr. Hurvitz's and Dr. Wesolowsky's testimony: vertebral artery disease is characterized by symptoms of "Drop attacks," that is, a sudden collapse of the legs due to muscle weakness without loss of consciousness which lasts only briefly. Other symptoms of vertebral artery obstruction are vertigo (a whirling sensation), diplopia (double vision), dysarthria (slurred speech), ataxia (a lack of muscle coordination), and weakness or numbness in the face, arms or legs (Exs. A-25, A-26, and A-36). It is those six symptoms more than any other which distinguishes vertebral artery obstruction from any other cause, but the so called "drop attack" is the sine qua non of the malady. Every witness who testified on the subject and all of the relevant literature note the importance of the "drop attack"[14] as a symptom of vertebral artery obstruction. Yet, nowhere in the records of, for example, patient Keith Anderson (Ex. A-58) does Dr. Hurvitz mention the existence of the drop attack symptom. This silence in the record is astonishing, coming as it does on

the heels of Dr. Hurvitz's testimony, in agreement with the literature, on the importance of the "drop attack" symptom to the diagnosis of vertebral artery obstruction. It amounts to substantial evidence against the Appellant on this issue.[15]

In this regard, the records of Judith Baker (Ex. A-59) do not mention a history or present symptoms of drop attacks; the patient simply could not stand. Although neck bruits, additionally, are a sign of vertebral artery obstruction, none were noted by Dr. Hurvitz. The same can be said for the records of Ann Boshart (Ex. A060) (no neck bruits recorded, no mention of drop attacks); Kenya Canterbury (Ex. A-62) (no neck bruits recorded, no mention of drop attacks); Sylvia Hall (Ex. A-64) (no neck bruits recorded, no mention of drop attacks); Sheila Harvey (Ex. A-65) (no neck bruits recorded, no mention of drop attacks); Helen Ives (Ex. A-66) (no neck bruits recorded, no mention of drop attacks); Donna Jones (Ex. A-67) (no neck bruits recorded, no mention of drop attacks); Margaret Zlemme (Ex. A-68) (no neck bruits recorded, no mention of drop attacks); Donna Lally (Ex. A-70) (no neck bruits recorded, no mention of drop attacks); Gail Morris (Ex. A-73) (no neck bruits recorded, no mention of drop attacks); Darlene Noffsinger (Ex. A-74) (no neck bruits

recorded, no mention of drop attacks); Louis Rozzi (Ex. A-75) (no neck bruits recorded, no mention of drop attacks); Leroy Russell (Ex. A-76) (no neck bruits recorded, no mention of drop attacks); Mark Simone (Ex. A-78) (no neck bruits recorded, no mention of drop attacks); John Subbert (Ex. A-79) (no neck bruits recorded, no mention of drop attacks); Alice Van Cleave (Ex. A-80) (no neck bruits recorded, no mention of drop attacks); and Richard Wilson (Ex. A-81) (no neck bruits recorded, no mention of drop attacks);. Indeed, out of 24 cases, fully 19 make no mention of drop attacks.[16]

Other evidence introduced at the hearing supports the finding that many if not all of these 24 patients' records lack proof of the existence of symptoms of vertebral artery obstruction. For example, four professors of medicine and also themselves physicians testified that none of the records in question document the existence of symptoms of vertebral artery obstruction.[17] This testimony is found to be more credible than that of the Appellant's witnesses, one of whom doubted even the existence of multiple sclerosis. Also, a review of the testimony and the literature reveals that a distinguishing feature of the transient ischemic attack and the cedes, as function of drug [illegible]

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"drop attack" (themselves solely the difference between vertebral artery obstruction and multiple sclerosis) is that they are "transient," lasting only very brief periods of time and debilitating the patient only for minutes or hours. Whereas, multiple sclerosis or the impression of an illness or condition one gets from reading all the records of all 24 patients, on the other hand, exhibits symptoms last for years and renders the patients continuously and progressively disabled. The persons described in the record do not, except perhaps for patient Law, have "transient" symptoms, but rather they show chronic, progressively worsening conditions prior to their operations.[18] Thus, for the foregoing reasons, the existence of symptoms of vertebral artery obstruction has not been shown. The Government, on the other hand, has shown to the satisfaction of the undersigned by a preponderance of the credible documentary and testimonial evidence introduced at the hearing that most if not all of the 24 patients under review did not have the symptoms of vertebral artery obstruction prior to their surgery.

IV. Other Causes

In addition to proving that symptoms of vertebral artery obstruction existed in each of the 24 patients' records in order

for vertebral artery surgery to be determined "medically reasonable and necessary," the Order amending the results of the pre-hearing conference requires that it be shown that other causes for the alleged impairment were considered and ruled out (Transmittal No. 715, Ex. R-1). As the evidence in the last section suggests, the Government labored mightily in this regard to show that most of the 24 patients in this case had multiple sclerosis or some other neurological malfunction, and to show that Dr. Hurvitz failed to consider, much less rule out, multiple sclerosis, or another neurological disease, as a cause of the symptoms.

For example, Dr. Thompson testified for the Government that seven of these patients' records showed signs and symptoms of multiple sclerosis, but that nowhere in Dr. Hurvitz's records was multiple sclerosis diagnosed, leading him to conclude that Dr. Hurvitz did not consider and rule out other causes such as multiple sclerosis before operating on the patients' vertebral arteries (TR: 1563-1564). He noted that between 60% and 75% of all multiple sclerosis patients have elevated gamma globulin in their spinal fluid which would "most definitely" alert a physician to the possibility of a diagnosis of multiple sclerosis, but that Dr. Hurvitz did not

indicate in 10 of his patients' records that he tested for gamma globulin (TR: 1547; 1586). Moreover, he pointed out that in order to clarify the diagnosis in 10 of Dr. Hurvitz's patients the Appellant should have performed a visual evoked response test and a screening blood test (TR: 1586-1587). These could have helped rule out multiple sclerosis, he stated (TR: 1587).

Moreover, Dr. Anderson testified that other causes were not ruled out by Dr. Hurvitz in 12 patients' records (TR: 445-597). Additionally, Dr. Rose testified that the records of 14 of the involved patients do not rule out other causes (TR: 1142). And Dr. Blinderman testified that there was nothing in the records of eight of the patients under examination indicating that Dr. Hurvitz considered "anything else" and that there was no differential diagnosis in the history or physical of the eight patients (TR: 1006-1026). Finally, Dr. Townsley noted that the records of eleven of the patients (TR: 1211-1212) are silent as to whether other causes for the patients' conditions had been considered and ruled out (TR: 1218-1219). He pointed out that in each patient's history, admitting diagnosis, and discussion of the diagnosis there is no mention of other possible causes for the patients' condition (TR: 1219). He was

of the opinion that an admitting physician such as Dr. Hurvitz should have a contrasting opinion from a neurologist substantiating any admitting diagnosis before vertebral artery surgery is performed, but that there were no such substantiating diagnosis in the eleven patients' files (TR: 1219)

Contrasting evidence was offered by Dr. Bonecutter who stated that Dr. Hurvitz "absolutely" ruled out other causes for all 24 of the involved patients' infirmities because the record demonstrates symptoms of vertebral artery obstruction, because there was radiographic evidence of obstruction, because no contradictions to the procedure existed, and because "neurological examinations and tests" ruled out other causes (TR: 1818-1819). Each of the 24 files, he stated, shows a history compatible with vertebral artery obstruction, shows neurological findings compatible with the disease of vertebral artery obstruction, and shows that Dr. Hurvitz performed a CAT scan, a P-12 serum determination, an EKG, a fasting blood sugar test, and chest and skull x-rays in order to consider and rule out other causes for the disease (TR: 1820)

Additionally, Dr. Woods testified for Dr. Hurvitz that in each and every on of the 24 cases under review, Dr. Hurvitz considered and ruled out other causes for the disease (TR:

2059-2060; Ex. A-90). On cross examination, Dr. Woods stated that although spinal fluid tests and CAT scans do not rule out other diagnoses, Dr. Hurvitz went through a "long list of procedures," including arteriography, to rule out other causes (TR: 2128-2132). He pointed out that before operating on the vertebral artery, a surgeon should obtain the patient's neurological history and that Dr. Hurvitz had not done so in every instance (TR: 2135-2136). Moreover, Dr. Wesolowsky testified for the Appellant that from his review of all 24 patients' files he was able to conclude that Dr. Hurvitz considered and ruled out other causes for each of the patients symptoms (TR: 2226-2320) based on the fact that the records in the file note that the patients had been seen by a neurologist some time prior to surgery and because blood tests, urine tests, EKG tests, CAT scans, x-rays, myelograms, and vitamin B012 tests were performed on admission (TR: 2226, 2243, 2248, 2256, 2261, 2263, 2264, 2267, 2270, 2275, 2278, 2281, 2283, 2286, 2288, 2290, 2294, 2296, 2302, 2304, 2306, 2310, 2314, 2317, and 2319). In many cases, Dr. Wesolowsky presumed that the prior neurological examinations revealed no other condition or cause for the symptoms but was unable to say so categorically based on his review of the

[illegible]

24 patients' records (TR: 2243, 2256, 2304, 2306, 2310, 2317, and 2319).

Finally, Dr. Hurvitz testified on this issue that he considered and ruled out other causes for the 24 patients' illnesses by, for example, taking a history, by performing a physical and neurological examination, and by performing CAT scan, angiogram, serum B-12 test, x-ray, blood sugar test, EKG test, blood count, syphilis test, test for hypertension, cystenography, and lumbar puncture (TR: 2633-2634, 2651-2652, 2673-2674, 2684-2685, 2697-2698, 2708-2709, and 2733-2734). On cross examination, Dr. Hurvitz agreed that an elevated gamma globulin is frequently seen in multiple sclerosis patients and that in some phases of multiple sclerosis between 60% and 75% or the patients have an elevated gamma globulin in their spinal fluid (TR: 93-94, red; Ex. A-25, P. 149). He noted that he did not order a spinal fluid analysis to check any of the 24 patients gamma globulin (TR: 93, red). He stated, further, that none of the 24 patients had hypertension although, according to the Government, probably the most important factor in the treatment of transient ischemic attacks is control of hypertension (TR: 94-95, red; Ex. A-36, p. 556).

Based on the above, the undersigned concludes that Dr. Hurvitz did not consider and rule out other causes for the patients' symptoms before operating on the vertebral arteries of the 24 patients under review. The Government has shown by a preponderance of the evidence that Dr. Hurvitz did not consider and rule out other causes. This is so for several reasons. There is substantial testimony in the record that many of the 24 patients had multiple sclerosis or some other neurological deficiency unconnected to the vertebral arteries. Three physicians testified at the hearing that many of the involved patients have multiple sclerosis or at least some neurological deficit (Doctors Thompson, Blinderman and Mileris). Several of the patients had previous diagnoses of multiple sclerosis or a neurological deficiency (Ex. R-74, R-76, and R-77). These diagnoses were available to Dr. Hurvitz or could have been available had he made the effort to get them. Moreover, most of the patients had a previous neurological examination by a neurologist. The results of these examinations were also available to Dr. Hurvitz. Yet Dr. Hurvitz chose to proceed with the operations, in several cases having followed the patient less than a day, with no review of the patients' past neurological examinations, with no referral

Based on the above, the undersigned concludes that Dr. rth did not consider and rule out other causes for the [illegible] symptoms before speculating on the [illegible] of [illegible] patients under review. The undersigned [illegible] a preponderance of the evidence that Dr. [illegible] did not consider and rule out other causes. [illegible] There a [illegible] in the record that [illegible] of the 26 patients had [illegible] of [illegible] deficiency [illegible] the [illegible] physicians [illegible] in the hearing that many of the [illegible] patients [illegible] or at least [illegible] ria). Several of the patients had previous diagnoses of [illegible] attributed to a neurological deficiency (Ex. [illegible] R-77). These diagnoses were [illegible] would have been [illegible] however, most of the patients had a previous [illegible] by a [illegible] patients' [illegible] to a neurologist for a current examination, with no spinal fluid analysis for a high gamma globulin count, and with no visual evoked response tests, despite the fact that vertebral artery obstruction can mimic multiple sclerosis, and in the face of the fact that vertebral artery disease is an illusive diagnosis. Even supposing that all 24 of these patients did not have a neurological disease or multiple sclerosis, the many indications in their records of positive neurological findings should certainly have led Dr. Hurvitz into a more thorough neurological investigation of the cause of the patients' problem than simply scheduling an operation the next day. However, this is not to say that Dr. Hurvitz did not, as he stated, perform many useful and necessary diagnostic tests, such as performing his own neurological examination, or obtaining CAT scans, or taking blood counts. But, given the substantial split of opinion in the record over the cause of these patients' symptoms and the certainty of some of the Government's physicians about the existence of neurological causes or of multiple sclerosis as the cause of the patients' impairments, it does not seem unreasonable to conclude that, given the divergence of opinion, Dr. Hurvitz really did not attempt to completely rule out other causes before performing his

operation. His records in this regard are deficient of the required proof. The Government has demonstrated to the satisfaction of the undersigned that Dr. Hurvitz did not consider and rule out other causes for all of these 24 patients' symptoms before operating on their vertebral arteries.[19]

V. Radiographic Evidence

Before a surgeon can operate on the vertebral artery of a Medicare recipient, Transmittal No. 715 requires that there be "radiographic evidence of a valid vertebral artery obstruction" (Ex. R-1). Radiographically demonstrable obstructions, according to the transmittal, include lesions inside the arteries which block blood flow, bony tissues which compress the artery and block blood flow, kinks in the artery which block the blood flow, and bends or slings which develop as a result of a neck injury or neck manipulation and block blood flow through the artery.[20] On this issue, as on the preceding issues, the parties submitted copious testimonial and documentary evidence, much of it repetitious. From it, however, a clear picture emerges.

In the files of 22 of the 24 patients, an arch aortogram report signed by the same radiologist, Ralph Burrows, M.D., highlights substantially the same findings for each: at the

origin of one of the two vertebral arteries there is said to be a "vague or oblique transverse radiolucent zone" but, each report continues, whether this vague zone represents any "intrinsic or extrinsic abnormality cannot be determined" (Ex. A-58 to A-80).[21] The other two files in the group of 24 under discussion, those of Kenya Canterbury and Ann Boshart (Exs. A-60 and A-62, or Exs. R-21 and R-23), contain no reports of any radiography, although the patient's x-rays were offered in evidence at the hearing (Exs. A-83a, A-84a, R-61, and A-98). Moreover, the x-rays of all the patients were submitted in evidence at the hearing (Morris, A-82a, R-68; Baker, A-82b, R-59; Russell, A-82, R-70; Sidentop, A-82d, R-71; Knauf, A-82c, R-66; Canterbury, A-83a, R-61; Hall, A-83b, R-63; Ives, A-83c, R-64; Boshart, A-84a, A-98; Jones, A-84b, A-99; Anderson, A-84c, A-96; Harvey, A-84d, A-97; Brayfield, A-84c, R-60; Noffsinger, A-84f, R-69; Green, A-84g, R-62; Klemme, A-84h, R-65; Lally, A-84, A-100; Law, A-84j, A-101; Monahan, A-84k, R-67; Rozzi, A-84l, A-102; Simone, A-84m, R-72; Subbert, A-84n, R-73; Van Cleave, A-84o, A-103; and Wilson, A-84p, A-104).

In addition, Dr. John Bentson, a neuroradiologist (TR: 4574), testified for the Government that here would have to be

a narrowing of "something like 50% of...normal" before an obstruction of a vertebral artery could be considered significant (TR: 4575. However, after reviewing the files and the patients' x-rays, he could not say that there was radiographic evidence of a valid obstruction in any of the 24 patients' vertebral arteries (TR: 4606-4696). The testimony of other Government physicians substantiates Dr. Bentson's view (TR: 109, 427-621, 985-1029, 1219, 1440-1500, 1502, 1565, 2115, and 4574).

Dr. Hurvitz testified in his own behalf on this issue that in each of the patients' x-ray files there does exist demonstrable radiographic evidence of a valid vertebral artery obstruction (TR: 2627-2896). Contrary to the Government's assertions, he stated, a 10% reduction in blood flow through the vertebral artery circuit can cause symptoms of vertebral artery insufficiency (TR: 2500-2501; Ex. A-48). Dr. Hurvitz noted that radiographic evidence of a valid vertebral artery obstruction can be manifested by radiolucent zones, kinks, a high aortic arch, a displaced vertebral origin, angulation, vertebral compression, tortuosity, bends, delayed filling, redundancy, opacification, or a highly resistant vascular bed (TR: 2509-2517; Exs. A-5, A-6, A-7, A-8, A-10, A-14, A-16, A-a narrowing of "something less than 50% of normal" before an obstruction of a coronary artery would be considered significant (Tr. 4679). However, after reviewing the films and the patients' charts, he could not say that there was angiographic evidence of a valid obstruction in any of the 24 patients' catheterization [illegible] (Tr. 4680-4699). The testimony of other Government physician consultants [illegible] Dr. Hornick's [illegible] (Tr. 189, 27-415, 989-1079, 1270, 1340-1356, 1583, 1584, 2118, and 2276).

Dr. Hornick testified [illegible] each of the patients' [illegible] angiographic evidence of a valid obstruction [illegible] (Tr. 3017-3083). Contrary to the Government's [illegible] a 10% [illegible] (Tr. 2895-2901, [illegible]) [illegible] angiographic evidence of a [illegible] [illegible] (Tr. 2895-2977; [illegible])

22, A-27, A-35, A-91, A-92, A-93, and R-85). Dr. Wesolowsky testified on Dr. Hurvitz's behalf after reviewing the patients' x-rays serially and simultaneously with the use of many view boxes that he could find obstructions in at least one of the vertebral arteries of each of the 24 patients here under review (TR: 2232-2320). Most of the 24 patients' x-rays were said to show a high arch and a lateral origin of the vertebral artery causing stenosis and delayed filling.

The best evidence on this issue of the existence of radiographic evidence of an obstruction, of course, is the arch aortograms. They ought to be allowed to speak for themselves concerning the existence or nonexistence of a valid vertebral artery obstruction. The trouble with that approach, however, is that in the interpretation of the x-rays, the Government's radiologists come to one conclusion (no obstruction) and the Appellant's physicians come to another conclusion (sufficient indication of an obstruction to warrant surgery). Moreover, relying exclusively on the x-rays themselves would not indicate to the untrained eye of the undersigned one way or another the existence or nonexistence of an obstruction. Therefore, because the x-rays are silent, the undersigned is forced to rely on the conflicting opinions of the experts. Thus, in weighing

the credibility, the expertise, and the competence of each physician who testified on the existence of an obstruction in the arch aortograms in the record, the undersigned concludes that their testimony taken together gives rise to a good faith doubt about the lack of an obstruction as seen on the x-rays. That is, the divergence of opinion, half of which would find an obstruction and half no obstruction, creates an inference that one could reasonably though mistakenly conclude that an obstruction may indeed appear on these x-rays, or that Dr. Hurvitz had reasonable grounds to hold a good faith belief, arguably incorrect though it may have been, that the x-rays show an obstruction. This belief coupled with the other evidence in the record and with an examination of the x-rays themselves by the undersigned creates a doubt as to the nonexistence of an obstruction. Therefore, giving Dr. Hurvitz the benefit of the doubt and relying on his reasonable, although perhaps mistaken, belief that the x-rays show an obstruction, the undersigned cannot conclude otherwise than that the Government did not show by a preponderance of the evidence that Dr. Hurvitz's x-rays did not indicate, at least in some good faith and reasonably believable way to Dr. Hurvitz, the presence of a valid vertebral artery obstruction. Thus,

although it is said that pictures do not lie, these pictures equivocate because, based on the conflicting interpretations superimposed on them by the experts, they do not unambiguously show that there is no obstruction of these 24 patients' vertebral arteries. For that reason, Dr. Hurvitz's reasonable, though perhaps misplaced, interpretation must prevail. His good faith belief that the x-rays show an obstruction, and his good faith reliance on the opinion of his radiologist, Dr. Burrows, that the x-rays show "abnormalities," are held to satisfy the third criteria that there be radiographic evidence of a valid vertebral artery obstruction before surgery on those arteries will be considered medically reasonable and necessary.

VI. Contraindications to the Procedure

The final criteria of the four criteria which must be satisfied before vertebral artery surgery can be considered reasonable and necessary under the Act is the requirement that "contraindications to the procedure do not exist" (Transmittal No. 715, Ex. R-1). The transmittal suggests a "coexistent obstruction of multiple cerebral vessels" as a possible contraindication to the vertebral artery procedure. This criteria puts a heavy burden on the Appellant to show

that there were no other methods of treatment for the symptoms more efficacious than vertebral artery surgery. In effect, it requires him to prove a negative.

In this regard, Dr. Anderson testified for the Government that vertebral artery surgery was contraindicated for twelve of Dr. Hurvitz's patients (TR: 445-597), and therefore that criteria number four was not met. He stated that a diagnosis of multiple sclerosis would be a contraindication to vertebral artery surgery (TR: 490). Moreover, Dr. Rose testified against Dr. Hurvitz that, in his professional opinion as a neurologist, a probable diagnosis of multiple sclerosis for 14 of the patients whose records he examined would be a contraindication to vertebral artery surgery (TR: 1113, 1125). He pointed out that vertebral artery surgery is not recognized as a medically acceptable procedure for treating or curing multiple sclerosis, and that Dr. Hurvitz is the only surgeon in the entire county that he know of who performs vertebral artery surgery (TR: 1008-1029). He testified in particular with respect to one patient's file that, "I don't see the indications for vertebral artery surgery. If you're doing it for the symptoms the patient presents with [spinocerebellar degeneration or multiple sclerosis], it's the wrong operation. If you're doing it for

some other disease, it would have to be life threatening" (TR: 1016). And finally, Dr. Thompson testified after examining seven of the involved patients' files that the probable diagnosis of multiple sclerosis for those seven patience would be a contraindication to vertebral artery surgery (TR: 1563-1565).

Predictably, Dr. Hurvitz and his witnesses made diametrically opposite assertions, maintaining, that there certainly were no contraindications to the 24 vertebral artery surgeries under review. Dr. Bonecutter pointed out based upon an independent review that in his opinion criteria number four was met in each of the 24 cases (TR: 1818-1819). As noted above, Dr. Woods certified in each and every one of the 24 cases that all four of the criteria fulfilled, including the nonexistence of contraindications to the vertebral artery procedure (TR: 2026; Ex. A-90). Furthermore, Dr. Wesolowsky testified that there were no contraindications to the vertebral artery operation for any of the 24 patients (TR: 2224-2320). Finally, Dr. Hurvitz testified in his own behalf that there were no associated conditions or diseases of a systemic, general, or local nature in any of the 24 patients that precluded or contraindicated the vertebral artery operation (TR: 2637-2896). He reiterated that the same general

observation can be made about all 24 patients (TR: 2754, 2761).

In light of this conflicting testimony and the difficulty in proving the negative, that is, that contraindications do not exist, it is the reluctant conclusion of the undersigned that neither side has proved its case on this issue and for that reason it has not been shown that conditions four was violated. The Government bears the ultimate burden of persuasion. The Government did not show conclusively that there were contraindications to the procedure such as coexistent obstructions of multiple cerebral vessels in these 24 patients' files. Dr. Hurvitz and his group, on the other hand, while not completely justifying the extreme of surgery for treating these 24 patients' symptoms, nevertheless introduced sufficient evidence at the hearing warranting a ruling in their favor. This vertebral artery surgery, in the opinion of the undersigned, was a drastic way to get what modest, if any, results were achieved. But it was not definitely contraindicated, on the other hand, by any conclusive proof introduced at the hearing. Although it may indeed be true that all of these 24 patients had multiple sclerosis or some other spinocerebellar disease or some other neurological observation can be made about [illegible] of [illegible] patients [illegible]

[illegible]

In light of this conflicting evidence and the difficulty in proving the negative, [illegible] it is the reasoned conclusion of the undersigned that neither side has proved its case on this issue [illegible]

[illegible] The Government [illegible]

[illegible]

deficit, the undersigned cannot conclude without a doubt that the patients had the diseases the Government propounds. If the patients do have multiple sclerosis, or the like, then that would be a contraindication to the vertebral artery surgery. But the undersigned does not know that the 24 patients have these diseases with certainty despite the strong evidence indicating that they do. Thus, since a doubt exists about the diagnosis of multiple sclerosis or the like and since that is the only major contraindication the Government advances, it cannot be said that there were contraindications to the vertebral artery surgery precluding Dr. Hurvitz from performing his operation. There is a doubt as to the existence of the only major contraindication advanced by the Government. The records, on the other hand, are silent on any other possible contraindication to the vertebral artery surgery. Therefore, the undersigned finds that the record lacks definitive proof that contraindications to the procedure existed prior to the surgery.[22] For that reason, it cannot be said that contraindications to the procedure existed.

VII. Findings and Conclusions

The undersigned finds that not all four of the Secretary's criteria for vertebral artery surgery contained in Transmittal infect, the undersigned cannot conclude without a doubt that the patients had the disease the Government represents. If the patients do have multiple sclerosis or the like, there [illegible] would be a contraindication to the vertebral artery surgery. But the undersigned does not know that the 15 patients were [illegible] diagnosed with [illegible] [illegible] [illegible] [illegible] indicating that they are. Thus, since a doubt exists about the diagnosis of multiple sclerosis in the 15 [illegible] [illegible] [illegible] any [illegible] contraindication the Government [illegible], it cannot be said that there were contraindications to the vertebral artery surgery precluding Dr. [illegible] from performing the operation. There is no dispute as to the existence of the other major contraindications [illegible] by the Government. The records of the [illegible] [illegible] [illegible] [illegible] no other possible contraindications to the vertebral artery surgery. Therefore, the undersigned finds that the [illegible] [illegible] [illegible] proof that [illegible] [illegible] to the [illegible] existed prior to the surgery [illegible] [illegible] [illegible] [illegible] [illegible] that contraindications to the procedure existed.

[illegible] Findings and Conclusions

The undersigned finds that [illegible] all of the [illegible] [illegible] the vertebral artery surgery conducted by [illegible]

No. 715 were met in the case of each of the 24 patients under review. The undersigned further finds, in particular, that not all 24 patients' files contain evidence of symptoms of a vertebral artery obstruction, show that other causes were considered and ruled out, contain radiographic evidence of a valid vertebral artery obstruction, and show that contraindications to the procedure do not exist. Thus, it is found that not all of the four criteria of Transmittal No. 715 were met in the case of each of the 24 patients under review.

In light of the substantial evidence introduced at the hearing and outlined above, the undersigned concludes that the Appellant's due process rights were protected by the procedural steps taken to exclude him from Medicare reimbursement coverage. As a consequence of the administrative process which was due to the Appellant, it was not an unreasonable exercise of the Secretary's discretion under 42 U.S.C. 1395y(d)(1)(C) for the Secretary to exclude the Appellant, S. Allan Hurvitz, from all Medicare reimbursement for a period of two years because he did not provide medically reasonable and necessary treatment in that he failed to perform vertebral artery surgery on the basis of proof in each case that symptoms of a vertebral artery

obstruction existed, other causes were considered and ruled out, radiographic evidence showed a valid vertebral artery obstruction, and contraindications to the procedure did not exist.

The two year exclusion imposed by the Secretary is reasonable and will be affirmed.

SO ORDERED.

EDWARD N. SCHIFF
Administrative Law Judge

Date: July 13, 1983

ENDNOTES

1. The two year exclusion, beginning on August 13, 1980 and ending on August 12, 1982, has been served and has expired as of the date of this decision (Ex. R-7).

2. The noted section of the Act provides as follows: Sec. 1862:

(d)(1) No payment may be made under this title with respect to any item or services furnished to an individual by a person where the Secretary determines under this subsection that such person--(C) has furnished services or supplies which are determined by the Secretary...to be substantially in excess of the needs of individuals or to be of a quality which fails to meet professionally recognized standards of health care."

3. A hearing was held over approximately 43 work days covering a year and one/half, from January 28, 1981 through June 18, 1982.

4. In this regard, it should be noted that the undersigned, in a February 5, 1982 Order amending the results of the pre-

hearing conference, resolved the second issue, by deciding that the noted four criteria are interpretative rules, and that as such the administrative law judge is "not bound by them." However, even though not bound, the undersigned has determined that the four criteria are not unreasonable and therefore will be applicable in the instant case.

5. Pursuant to 42CPR 405.1561, either Dr. Hurvitz or HCFA, or both, may request in writing that the Appeals Council, Arlington, VA, review the instant decision. Under 42 CPR 405.1562, the request for review must be accompanied by whatever additional material the requesting party desires the Appeals Council to review, and it must contain a statement specifying the issues or findings or conclusions with which the requesting party disagrees along with the reasons or basis for the contention that the particular issues or findings or conclusions are incorrect.

6. The vertebral artery surgeries under scrutiny in this case are determined to have been substantially in excess of the needs of the patients on whom performed; the quality of the operations, moreover, failed to meet professionally recognized standards of health care. 42 U.S.C. 1385(d)(1)(C).

7. The Appellant alleges that he was denied due process of law because of the way his waiver of liability was withdrawn; because he was denied a full evidentiary hearing prior to the imposition of sanctions; because UCFA did not comply with its own regulations and manuals; because notice of the "criticism" against Dr. Hurvitz was not provided; because there was not rational basis for concluding that the Appellant was unwilling or unable to comply with the law; because voluntary or educational methods of achieving compliance were not attempted; because HCFA did not specify Dr. Hurvitz's "wrongdoing" with factual findings; because HCFA relied on ineligible reviewers, ineligible opinions, and invalid criticism to substantiate it sanctions against Dr. Hurvitz; because HCFA did not accept the findings of a committee at one of the Appellant's hospitals; and because the decision to impose sanctions was based on nonspecific guidelines and instructions. The Appellant also alleges that no weight should be given to medical transmittal No. 715.

8. Partially in order to contain exorbitant medical costs, the 1972 amendments to the Social Security Act provided for the creation of Professional Standards Review Organization

(PSROs) which were designed to involved local practicing physicians in an ongoing review and evaluation of health care services covered by Medicare and other federal health care programs. 42 U.S.C. 1320c through 1320c-19. To carry out its duties under the Act, 42 U.S.C.1320c-3(a)(1), each PSRO is empowered to request a practitioner to furnish evidence of the necessity or the quality of covered care. 42 U.S.C. 1320c-9(a)(2). A PSRO is also allowed to exclude from participation , with the concurrence of the Secretary, any physician found to have failed to comply with his or her obligations under the Act. 42 U.S.C. 1320c-9(b)(1). Each PSRO can prevent the expenditure of federal funds for medical services found not to be medically necessary. 42 U.S.C. 1320c-7. Medically professional norms of diagnosis and treatment for various illnesses and conditions were established by the amendments. 42 U.S.C. 1320c-5(b).

The constitutionality of the noted scheme has been affirmed. Association of American Physicians v. Weinberger, 395 F. Supp. 125 (N.D.Ill. 1975), aff'd 423 O.S. 975, 96 SCt. 388, 46 L.Ed.299 (1975).

9. The withdrawal of waiver of liability status for Dr. Hurvitz by Area 22 PSRO on February 20, 1979 because of his performance of vertebral artery surgery was not a step in the process of excluding him from Medicare reimbursement under 42 U.S.C. 1320c-8; any alleged or real irregularity therein is not relevant to the issues in the dispute in this case.

10. Evidence was introduced at the hearing on the symptoms of multiple sclerosis, namely, spasticity in 90% of all cases, muscle weakness, contracture of the muscles, loss of coordination, urinary retention, urinary incontinence, constipation, pressure sores, headaches, vertigo, depression, and anxiety (Ex. R-95, pp. 17-33).

11. Dr. Hurvitz stated that the symptoms of multiple sclerosis include motor disturbance, sensory disturbance, impaired vision, diffuse neurological signs, euphoria, lack of insight, excitement, and maniacal states, all of which are subject to repeated long term cycles of remission and exacerbation (TR:L 34-35, red). He compared the differences between multiple sclerosis and vertebral artery obstruction (TR: 35-37, red) and then noted the symptoms peculiar to vertebral artery

obstruction in the 24 patients' records here in dispute (TR: 37-41), most of which according to Dr. Hurvitz involved drop attacks, a disorder of equilibrium, vertigo, or dizziness.

12. There is confusion in the record in the use by the parties of the terms "obstruction" and "insufficiency" when referring to the blockage of blood through the vertebral arteries. Although Transmittal No. 715 requires that an "obstruction" be shown and although the pre-hearing agreement on the issues requires that "obstruction" be proven, the parties interchangeably use the two terms. Thus, either use will be taken to mean "obstruction" by the undersigned unless a contrary intent appears. For example, although Dr. Blinderman described an "obstruction" as having symptoms of brain stem infarction and death, his testimony is taken to mean that vertebral artery obstruction, as here defined, exhibits symptoms more akin to that which all other physicians testified to, namely, transient attacks, drop attacks, double vision, and the like, which he termed symptoms of vertebral "insufficiency."

13. Because of the existence of symptoms of an obstruction in each of the 24 patients' records has not be shown by a preponderance of the credible evidence introduced at the hearing, examination of the remaining evidence and testimony on the other issues (other causes, radiographic evidence, and contraindications) is not necessary because it is Dr. Hurvitz's burden under Transmittal No. 715 to show that all of the four criteria have been met, and he cannot do so if the first lacks proof. However, in order to render a complete, on-the-record review of the evidence on all issues together with findings, reasons, and conclusions, the remaining issues will also be examined.

14. A "drop attack" is defined as a sudden loss of postural tone resulting in a fall to the floor or ground without loosing consciousness, after which the subject immediately regains postural control and rises quickly. P. Beeson and W. McDermott, Textbook of Medicine, p. 198, Thirteenth Edition.

15. The fact that Dr. Hurvitz's records for this patient show that Mr. Anderson had "four plus Romberg testing with falling," which is the closest Dr. Hurvitz comes to describing a drop attack, does not overcome the above finding. A positive

Romberg test is not a sign of a drop attack in progress or of a transient ischemic attack in progress. Rather, nystagmus and neck bruits are signs of such attacks. But the noted records specifically state that there were no neck bruits and that there was no nystagmus when Dr. Hurvitz examined the patient, and no history of such either. Additionally, the fact that Mr. Anderson had a problem with his balance during Romberg testing, and had a history of a loss of balance and equilibrium, does not supply the missing symptom of a "drop attack" nor thereby prove the existence of vertebral artery obstruction in order to satisfy the first criteria of Transmittal No. 715.

16. Simply because many of the 19 patients developed a "progressive disorder of equilibrium, balance, and gait" and that some of the patients experienced "falls" of one sort or another does not substitute for Dr. Hurvitz's failure to record or mention the "drop attack" symptom of a sudden loss of postural tone resulting in a fall without loss of consciousness and then immediate recovery. There is nothing in the records of the noted 19 patients to suggest sudden, immediate, or quick falls coupled with rapid recovery. Moreover, the records of patient law (Ex. A-71) distinguish between "falls"

and "drop attacks," and thus indicate that when Dr. Hurvitz found a history of or found symptoms of a "drop attack" he noted it, but that otherwise he documented only a "fall" due to a disorder of equilibrium, balance or gait.

17. See the testimony of Drs. Thompson, Anderson, Rose, and Blinderman, above.

18. The alleged or real "placebo" effect of Dr. Hurvitz's vertebral artery operation on these patients, although the subject of not a little testimony and documentation in the record, is not properly before this hearing body for a decision.

It is not one of the four criteria in Transmittal No. 715. It is not one of the issues in the Order setting forth the issues for hearing. It is, thus, not relevant to these proceedings and for that reason will not be considered further.

19. Transmittal No. 715 (Ex. R-1) states that "other causes" must be considered and ruled out. It lists several differential diagnoses, including degenerative disorders of the brain, orthostatic hypotension, acoustic neuroma, labyrinthitis,

diabetes mellitus, and hypoglycemic disorders as other causes which must be considered and ruled out. At the hearing, there was no proof that all of these causes, quite apart from multiple sclerosis, were considered and ruled out in each of the 24 patients' records under review.

20. Transmittal No. 715 recommends that angiograms show the aortic arch, the vessels off the arch, the vessels in the neck, and the vessels in the head. Biplane views and serial views are also recommended (Ex. R-1).

21. Of the 22 files noted above, all contain the equivocation about "intrinsic and extrinsic abnormalities" being indeterminate, while 21 of the 22 contain references to "vague or oblique transverse radiolucent zones." Dr. Woods testified, after reviewing Dr. Burrows' arch aortogram reports, that "...the x-ray man quibbles" (TR: 2113-2114).

22. Placing the burden of proof on the Government on this issue, as on all the issues above, relieves Dr. Hurvitz of proof of the negative. It would be fruitless to require the Appellant to run down a list of every conceivable contraindication to the

procedure and then prove that it does not exist in these 24 patients' files. It is enough to let the files speak for themselves. Although they strongly suggest multiple sclerosis or another neurological deficit, they do not prove the contraindication conclusively.

SECRETARY'S INITIAL DECISION-SANCTION

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Health Care Financing Administration
Baltimore, Maryland 21235

Refer to:
FNV23

July 29, 1980

S. Allen Hurvitz, M.D.
2080 Century Park East
Suite 508
Los Angeles, CA 90067

Dear Dr. Hurvitz:

By letter dated January 15, 1980, you were notified by Mr. Don Nicholson, Director, Office of Program Validation, of the proposal to exclude all items and services furnished by you from reimbursement under the Medicare program. At that time, you were given the opportunity to appear before a representative of the Health Care Financing Administration to submit evidence and testimony relevant to the proposal of exclusion.

After considering the written information and oral testimony presented at the administrative review on April 29, 1980, I have determined that the proposed exclusion should be put into effect. I am, therefore, excluding all items and

services rendered by you from reimbursement under the Medicare program for a period of 2 years. The authority for this determination is contained in section 1862(d)(1)(C) of the Social Security Act.

The action is being taken for the reasons described in the enclosed decision. The exclusion will be effective 15 days from the date of this letter. As of that date, Medicare will no longer make payments for items and services provided by you. As a result of this exclusion, Federal funding of the title V and title XIX programs, with respect to items and services furnished by you, will be discontinued. As required by the Social Security Act, we will place a legal notice in a local newspaper to advise the community of the effective date and the reasons for this exclusion.

At the conclusion of the 2-year period, or at any time thereafter, you may be eligible for reinstatement to the program. If you desire readmission, you should apply to the Health Care Financing Administration at least 90 days prior to the date on which you want to be reinstated. Upon receipt of such a request, you will be advised of the information and documentation required for us to reach a decision regarding your reinstatement. If you do not believe this decision is

correct, you may request a hearing before an Administrative Law Judge of the Social Security Administration. To be effective, a written request for a hearing must be filed not later than 60 days after the date of this letter.

Evidence and arguments may be presented at the hearing and you may be represented by counsel. Such a request should be made to the Health Care Financing Administration, Office of Program Validation, Room 2-E-5 East Low Rise Building, 6401 Security Boulevard, Baltimore, Maryland 21235.

Sincerely yours,

Martin L. Kappert
Acting Director
Bureau of Quality Control

Enclosure

cc:
Health Services Administration,
  Public Health Service
Bureau of Program Operations, HCFA
San Francisco REgional Office:
  HCFA Regional Administrator
  Office of Program Integrity
  Medicare, Medicaid
Director, HSQB
Mr. Robert Hinerfeld, Attorney
Area 22 PSRO
California Statewide PSR Council

The standards are clearly defined and were known to Dr. Hurvitz. The standard that a valid obstruction must be documented by radiographic evidence in order for surgery to be determined to be medically necessary is not an unreasonable one. To accede to performing surgery on the basis that no one is hurt and some do improve is highly unscientific and poses clear risks to the well-being of beneficiaries.

In conclusion, Dr. Hurvitz has failed to present any new information which refutes the finding of the Area 22 PSRO that he did perform services which substantially exceeded the needs of the individuals. The record also reveals that he is committed to continuing to perform this procedure.

DECISION

It is my decision that all items and services furnished by Dr. Hurvitz should be excluded from Medicare reimbursement for a period of 2 years.

Martin L. Kappert

Acting Director

Bureau of Quality Control

CERTIFICATE OF SERVICE

I hereby certify that on this 8 th day of October , 1988, three copies of the Petition for Writ of Certiorari were mailed, postage prepaid, to Solicitor General, Department of Justice, Room 5614, Washington, D.C. 20530, Counsel for Otis R. Bowen, Secretary of Department of Health and Human Services, Respondent. I further certify that all parties required to be served have been served.

S Allan Hurvitz

S. ALLAN HURVITZ, MD
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Suite 508
Los Angeles, CA 90067
Tel.: (213) 477-5575
Petitioner In Pro Se